Metals and Engineering in Bone and Joint Surgery

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CHARLES ORVILLE BECHTOL, M D

Professor of Orthopedic Surgery and Chairman of Orthopedic Division, University of California, Los Angeles, Chairman of Subcommittee on Testing, Prosthetics Research Board, National Research Council

ALBERT BARNETT FERGUSON, JR , M D

Silver Professor of Orthopedic Surgery, and Chairman of Orthopedic Department, University of Pittsburgh, Children's and Presbyterian Hospital, Pittsburgh, Consultant, Orthopedic Surgery, U S Veteran's Hospital, Oakland, Pittsburgh, St Margaret's Hospital, Pittsburgh, Green County Hospital, Waynesburg

PATRICK GOWANS LAING, M B , B S , F R C S

Assistant Professor of Orthopedic Surgery, University of Pittsburgh, Chief of Orthopedic Service, U S Veteran's Hospital, Oakland, Pittsburgh



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PREFACE

In dealing with the vast and complex problems of reconstructive bone surgery and some of the more complicated fracture problems, one of the surgeon's greatest allies is the use of metal for internal fixation or replacement of portions of bone This requires that surgeons understand and be able to apply both the biological and engineering principles involved The biological and engineering principles, however, frequently come into conflict, and under these circumstances a compromise must be made to give the best possible result under the circumstances The purpose of this book then is to gather the biological and engineering principles together so that the surgeon may more readily understand them and may be aided in making these necessarily difficult decisions Those surgeons dealing with bone and its problems will necessarily have to learn more and more engineering as new and more complicated operations are devised In our attempts to roll forward the frontiers of surgery and to have increasingly successful procedures to combat the damages of disease and injury we have purposely avoided going into the more technical aspects since excellent texts are already available Students who wish to approach this problem more seriously are advised to study texts such as *Basic Structures* by F R Shanley *Photoelasticity* by Frocht, to study the principles of stress distribution and stress concentration, and the *Fatigue of Metals* by R Cazaud to define the problems related to this very complex subject Engineers are becoming increasingly interested in the aspect of human engineering and consultation with an engineer should be sought when dealing with some of the more complicated problems in the research field

It is intended to bring to those practitioners of medicine who seek understanding of the skeletal system and of the metals used to preserve it some fundamental background knowledge for their work A prolonged interest and research in engineering principles as related to the locomotor system resulted in the accumulation of much fundamental data A similar accumulation of relevant facts from the fields of metallurgy and corrosion engineering has been obtained over the years The application of this knowledge and research in the field of metal inserted in the human being led to the feeling that this background material should be readily and conveniently available to the medical profession It has been accumulated by the authors at the expense of considerable time and effort

It was fortunate that the interests of the authors in this general bio

mechanical field did not overlap, and a natural union of manuscripts was accomplished through the miracle medium of modern day communication One author was the stimulus to another and every effort has been made to present technical material in usable form for the practitioner of medicine and surgery

The production of the manuscript has involved the devoted work of our secretaries Sally Byrnes and Mary Cosgrove, who were able to add this tedious work to their other duties without complaint Hubert Schwartz photographed the many metal specimens and roentgenograms except for those illustrations furnished by the Crucible Steel Company and the International Nickel Company, to all of whom we are eternally grateful

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1

HISTORICAL USE OF METALS IN THE HUMAN BODY

Albert B Ferguson, Jr , M D

As soon as a metal began to be used for the internal fixation of fractures there were two opposing camps in regard to its use

As early as 1775, physicians were in dispute over the internal fixation of fractures[1] Iron wire was the first metal used to fix bone With sepsis as the order of the day it was very difficult to discern whether the use of metal increased the incidence of infection Since any operative procedure was fraught with grave danger it is easy to understand that the open reduction of fractures could hardly have widespread acceptance

Levert made the first study of tissue tolerance to metal After a series of experiments on dogs in 1829 he concluded that of all the buried wire sutures that he had tested platinum wire was the least irritating He had tested gold, silver, and lead as well Lister[3] himself had successfully used buried silver wire sutures to hold bone under cover of antisepsis

Malgaigne[4] in 1849 tried to skirt skillfully through the possibility of the metal being the source of "hospital gangrene" by devising adjustable metal hooks that pierced the skin to hold the fragments together The hooks were withdrawn once early repair had taken place

The name of Hansmann[5] is attached to the first inserted metal plates The screws for these plates and one end of the plate itself (which was bent at a right angle) projected from the wound for easy removal four to eight weeks later These plates were described in 1886 It was not until 1900 however that plates and screws were used to any extent in fresh uncomplicated fractures The development of the use of roentgen rays revealed poor reduction in what had previously been termed acceptable practice and stimulated the use of internal fixation

There were many materials and shapes used these early days Lambotte[6] of Brussels advised brass plates at the turn of the century, but

the alignment of the connective tissue cells and fibers was axial along the expected route of the electric current produced This current also seemed to be stimulating enough to result in rhythmic muscular contractions

When Von Baeyer inserted rolls of copper and zinc beneath the skin of rabbits for several months he observed other changes The copper remained shiny apparently with copper ions migrating to the zinc and plating it Since other metal combinations appeared to accelerate corrosion, which he noted as the rusting of steel, he felt that various combinations of metals deserved further study, possibly finding for them some useful purpose

Before metal could be used as an implant with much success it was obviously necessary to be able to get it into the body without bacterial contamination The failures caused by electrolytic reaction and to sepsis could then be separated Lane[8, 9] introduced his "Lane technique" for this purpose since he found that much greater precautions (as regards asepsis) were necessary to prevent infection when operating on bone and using internal fixation Using his "no touch" technique, he stated that he had never seen the so called "rarefying osteitis" which he regarded as caused by infection rather than by the presence of the metal itself His results were the first truly successful series of bone plating Without such a masterful technician to emphasize technique the use of metals for internal fixation, when indicated, might still be waiting for a champion to prove that their hazards could be reduced to a safe level

Stanley and Gatellier[10] found that early ossification was delayed when Parham bands were used about fractures but did not find any evidence of toxic reaction of iron salts It was left to Leriche and Policard[11] (who examined the tissues about these bands histologically and chemically) to determine that the bone was necrotic and the tissues heavily impregnated with iron

A thorough study of tissue tolerance to metals was done by Hey Groves[1] He used various metals in the form of plates, screws, and intramedullary pegs and came to the following conclusions, based on gross observation

1 Nickel plated steel has no irritating effect on the tissues

2 Magnesium is rapidly absorbed and acts as a powerful stimulant to bone formation

3 Indifferent aseptic bodies are readily tolerated by the tissues

It is worth noting that Hey Groves[1] reported on the use of an intramedullary bar for comminuted fractures in 1913

An unfortunate series of three fractured bone plates in 55 fractures of the middle third of the femur induced Sherman[13] of Pittsburgh to have



Fig 1 Joseph Lister successfully used buried silver wire sutures for the internal fixation of fractures (By permission of Surgery Gynecology and Obstetrics 1912)

by 1909 was reporting that he had also used aluminum, silver, and red copper All were discarded as being too malleable A very predictable result occurred when he tried steel screws and magnesium plates The disintegration was so rapid that the fracture was still unrepaired when the metal vanished His final recommendation in 1909 was a soft steel plated with gold or nickel

It was felt at this time that the reaction of metals in the tissues could be put to some use Von Baeyer[7] in 1908 described the cellular reaction about bits of metal left buried in the tissues for varying periods of time He found that when cooper and zinc were implanted close together that

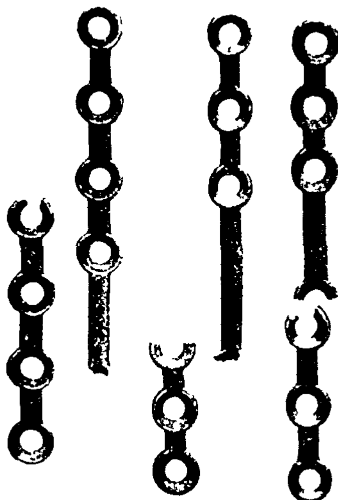


FIG 3 Sherman became interested in the plate design and the metal used when he had three failures of the Lane plate These are illustrated above with the fracture occurring at the junction of the first screw hole and the center bar (By permission of Surgery Gynecology and Obstetrics 1912)

have a bending of the plate instead of a break The addition of vanadium to a high carbon steel intensifies the hardening elements making the steel more dense and tough thereby increasing the elastic ratio, *i e*, ratio between the elastic limit and elongation It would take great force to bend a vanadium plate sufficiently to break it

Sherman patterned his plates after the standard "eye" bars used in bridge constructions He reduced the number of screw eyes in the plate, pointing out that the same end could be achieved by increasing the distance between the eye's so that no more than six screws were necessary to fix securely and hold a plate in position By Sherman's design less steel was actually used in a stronger plate

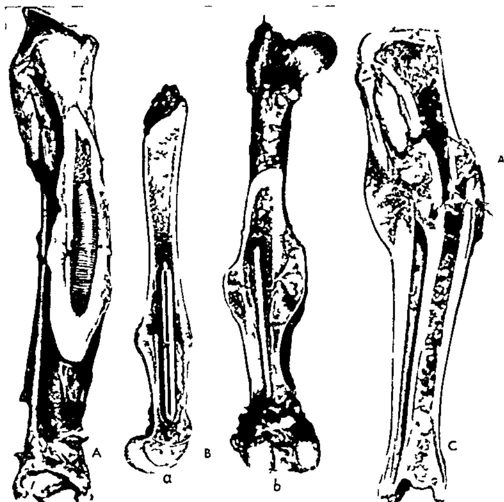


Fig 2 (A) An intramedullary coil spring used experimentally in a cat's tibia by Hey Groves from his article in the British Journal of Surgery 1913 (B) An intramedullary metal bar used to immobilize an experimental fracture in the femur of a cat after 42 days at both (a) and (b) (C) Cat's tibia after the use of magnesium intramedullary peg (66 days) A marks the remains of the peg which has largely disappeared There is an excess of callus (From Hey Groves E W An experimental study of the operative treatment of fractures Brit J Surg 1 438 1913)

a second look not only at the metal used, but also the design of the plate One plate broke as the operative dressing was being applied The break in the Lane plate always occurred at the same point, that is the junction of the central metal bar and the first screw hole

Previous bone plates were made of high carbon tool steels He noted that high carbon steels possessed great elastic limits but were weak in ductility (toughness and bending properties) The ideal steel for a bone plate in Sherman's words is "one that has a sufficient elastic limit with greatest ductility so that in case a strain should be exerted we would

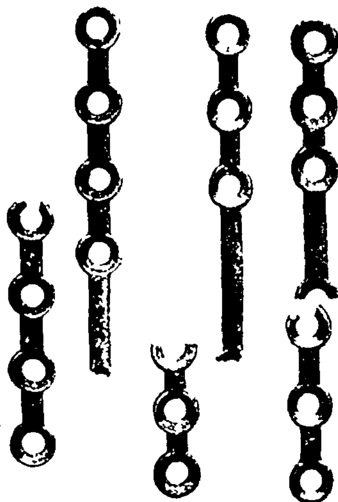


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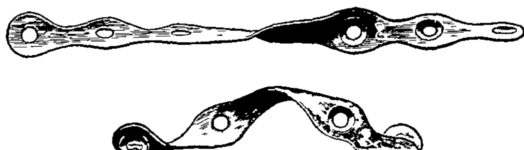


Fig 4 Sherman emphasized that the metal used in bone plates should have the property of bending without breaking The plates drawn here are of vanadium steel after bending tests

Sherman discussed metals further discarding silver as being of too low an elastic limit to have much value Aluminum, he found, was just the opposite as it possessed a high elastic limit but lacked bending properties He removed 17 vanadium plates in 55 cases and found that, if removed after six weeks, the surrounding tissues were often stained with iron, but noted that this did not seem to interfere with satisfactory progress of the case He espoused self tapping (fluted) screws of a machine type as compared to a wood screw design His work put the internal fixation of fractures when it was clinically necessary, on a firm basis and greatly reduced the number of failures from metallurgical and engineering causes

Zierold in 1924 studied the reaction of bone to various metals with the object of determining whether the metal exerted an influence on the bone other than that of any foreign body He used mature dogs as his experimental animals and tested gold, silver aluminum, zinc, lead, copper, nickel high carbon steel low carbon steel, stellite copper, aluminum alloy magnesium and finally iron Observations were macroscopic of the metal and bone supplemented by histological sections of the bone and roentgen examination of the inserts

Some metals such as copper showed a marked overgrowth of bone about the metal Gold silver stellite lead and aluminum seemed to Zierold to form a group which were well tolerated The other metals interfered with the usual process of regeneration and bone repair Discoloration of tissues and failure of the tissues to cover the metal implant were seen when the latter were studied Although he found that gold, aluminum and stellite were readily tolerated by bone and tend to become encapsulated Duval [14] Elberg[15] and Danbourn[16] had previously observed that aluminum was absorbed in the tissues

A case in which an aluminum plate lay on the humerus in close contact with the radial nerve dramatically demonstrated the current produced by dissimilar metals When a brass screw was brought into contact

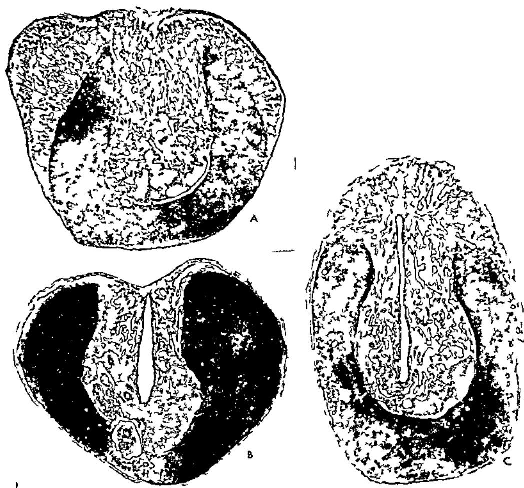


Fig 5 The following drawings were made to illustrate experiments performed by Zierold (A) Iron section of control tibia A 5 mm hole was drilled in the tibial cortex and this drawing illustrates the normal ossification repair (B) Showing the tibia cross section after removal of a small gold implant which had been placed in the 5 mm hole The metal was in place for six weeks and good bone repair had taken place (C) Cross section of the area where an aluminum implant was used Bone repair is obviously diminished but still present

with the plate there was extension of the hand and fingers Orsos,[17] who reported this case, was of the opinion that an appliance of homogeneous metal only should be used

The electrolytic phenomenon has been emphasized by many Masmonteil[18] measured the potential difference between the corroded and noncorroded portion of the screws in three cases in which fairly profound corrosion of the screws had occurred The potential varied from 0 134 to 0 153 mv

Venable and Stuck[4] are responsible more than anyone else for alerting American surgeons to the phenomenon of electrolysis in connection with metals In 1937 Venable, Stuck, and Beach[19] placed screws in bones of

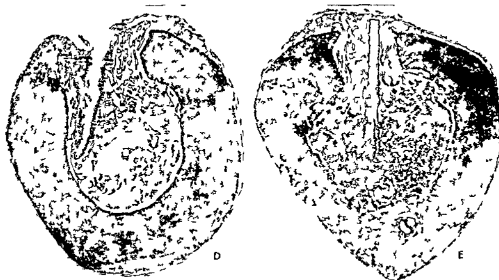


FIG 5 (D) Cross section showing region of high carbon steel implant with virtual failure of repair (E) The region of a stellite implant Note that bone repair took place over the implant site Note that in some illustrations the bone failed to clo e about the implant Zierold felt that gold aluminum and stellite were well tolerated by bone (From Zierold A A Reaction of bone to metal Arch Surg 9 365 1924)

experimental animals The metals used were vitallium, copper, brass, galvanized iron vanadium steel plain steel and copper, both chromium plated and silver plated They found that all the metals except vitallium produced absorption in the bone and became loose Venable and Stuck[4] in their very complete work on internal fixation heavily emphasize the electrochemical relation of metals Further work has emphasized still other aspects of metals in tissues

Magnesium has been entertained repeatedly as a possible material for bone fixation The disappearance of the metal with the formation of gas in the tissues gives an indication of the rate of its reaction in the body McBride[9] evinced interest in its use as an alloy in 1938, noting the phenomenal stimulation of periosteal proliferation It was heartily condemned at the time by both Key and Venable

A new stainless steel 18 8 S mo steel containing 16 to 20 per cent chromium a maximum of 14 per cent nickel and 2 to 4 per cent molyb denum was contrasted with vitallium by Key[21] He inserted screws in the femur of dogs and found none of the screws of either metal loose after 13 months After summarizing the two metals from the standpoint of me chanical properties he felt that the mechanical advantage of the 18 8 S mo steel outweighed its slight tendency to corrosion and recommended it over the vitallium of that era

Campbell and his associates had been interested in investigating the

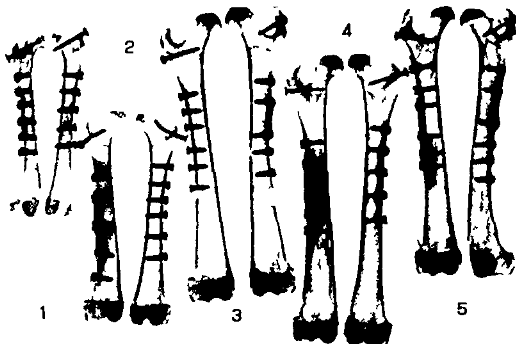


Fig 6 Key placed screws and nails in the paired femurs of 5 dogs This illustration shows tho e femurs on removal 13 months later The right femurs contained screws and nails of vitallium The left femur contained stainless steel Both metals appeared very well toler ated (From Key J A Arch Surg 43 615 1941)

cytotoxicity of ticonium This alloy came in two forms The casting alloy was quite brittle in the hardened condition and had a composition of nickel 33 6 per cent cobalt 29 1 per cent, chromium 27 7 per cent molybdenum 6 0 per cent, beryllium 1 6 per cent The beryllium added to the alloy enabled it to be cast with high fidelity The wrought alloy was essentially the same lacking the beryllium

In 1941 along with ticonium the following metals were tested gold, silver vitallium stainless steel, vanadium steel, and copper The toxicity of the metal was determined by the rate of growth of a pure fibroblast culture in the presence of the different metals On the basis of this observ a tion gold silver ticonium vitallium, and stainless steel were found to be nontoxic Vanadium and copper were found to be highly cytotoxic

The importance of tissue injury as contributing to the electrolytic effect publicized by Venable and Stuck began to be voiced by some Blunt Hudack and Murray[23] at a symposium on the metallic fixation of fractures sponsored by the American College of Surgeons in 1939 voiced some of these thoughts He pointed out that the mere trauma of opera tion was sufficient to set up a difference in potential of 100 mv between the injured tissue and the adjacent normal tissue A question was raised Did the metallic plate intensify or prolong that reaction? Many became



FIG 7 A vanadium steel plate after 30 years Note the osseous proliferation about the screws and plate and the loss of clear outline of the screws because of their disintegration and partial destruction

convinced that the degree of calcium deposition at the site of fracture was dependent on the degree of ionization present in the tissues at the fracture site Murray used a system employing a Quin Hydrone electrode *inserted directly into the tissues at the fracture site to test this* So long as an acid hydrogen ion concentration existed at the fracture site no calcium deposition occurred It was noted that lack of mechanical rigidity at the fracture site produced acidity apparently caused by a mechanical inflammatory reaction regardless of the type of immobilizing appliance Hudack[24] presented some observations based on experimental evidence at the same time It was obvious to him that the metal used should have resistance to surface corrosion and resistance to fatigue failure Vanadium steel under the vibratory stresses present when used as the rigid fixation at a fracture site had suffered intermolecular corrosion as the result of fatigue making it liable to fracture He found that the same phenomenon was not found when ' 3 phase high chrome, low nickel steel " was used It was found that both casting and stamping impaired the necessary *physical qualities of the metal*

A nonabrasive polishing of the surface appeared necessary, preceded by a passivation of the surface by an acid bath The results of the 1939 symposium appeared to indicate that the composition of the metallic fixation used and the rigidity and adaptability of the fixation to physical strain and stresses appeared to represent the basis of a possible solution to the question of operative fixation

It was obvious that vanadium steel after a reign of 20 years was on the way out

Venable warned against the use of vitallium and stainless steel screws

or plates in the same fixation device. Key[25] underlined this statement, but remarked that the danger is perhaps even greater when two different types of stainless steel are used. The result could be progressive bone resorption from electrolysis or failure of the intended operative result.

Hand and Lyon[6] have emphasized the mechanical aspect of the application of bone plates in an effort to eliminate metal failure. The side pressure exerted on screws when not perfectly centered in the hole of the plate was noted by them. The improved holding power of coarse threaded screws as compared to fine threaded screws made them favor the former. The fact that the metal used modified this holding power somewhat was also emphasized. Screws should be set through both cortices and when a six hole plate was so held it appeared to Lyon and his associates[7] that a 1½ ton pull was necessary to tear the plate out.

Then World War II brought a sense of urgency to the definition of the most desirable metal for use in internal fixation.

The orthopedic committee of the National Research Council assigned a project rated Class A to Murray and Fink in order to get a quick determination of the most acceptable metal alloy for use in the human body. These studies were later extended by Fink and Smatko. The work of Fink and Murray resulted in the recommendation of type 302 steel to the Army and Navy in 1943.

Fink and Smatko's work was reported in 1948.[8] They had tested three different stainless steels and one chromium cobalt alloy, all in the form of plates or screws. The corrosive media used included physiological saline, plain serum, serum saturated with an excess of sulfanilamide, serum inoculated with *Staphylococcus aureus*, and serum acidified to pH 5.0 to 5.5 by potassium acid phosphate. The results showed that type 302 steel was the most corrosion resistant. They were mindful of Murray's work pointing out that the pH was 5.6 immediately after trauma and rose, as healing progressed, to a final pH of 7.35. No gross changes in weight were noted in any of the four different kinds of bone plates. Although type 302 made the best performance, the margin was very slight. The other alloys were 316 steel and vitallium. Straining resulted in a perceptible increase in weight loss. The objection to vitallium at that time was based on its physical properties rather than its corrosion resistance which was excellent. It was felt that further changes in the manufacture of vitallium might eliminate these objections.

There was still more to be said about implant materials as the results of research begun after World War II became known.

Blunt, Hudack, and Murray[3] reported on investigative work done for the Committee on Fractures and Other Trauma of the American College of Surgeons. They investigated and defined the following

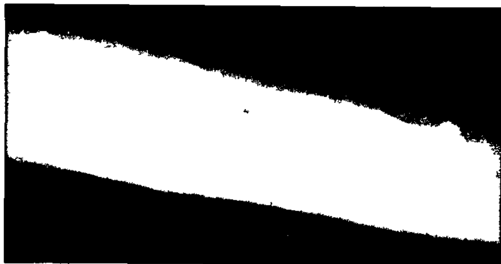


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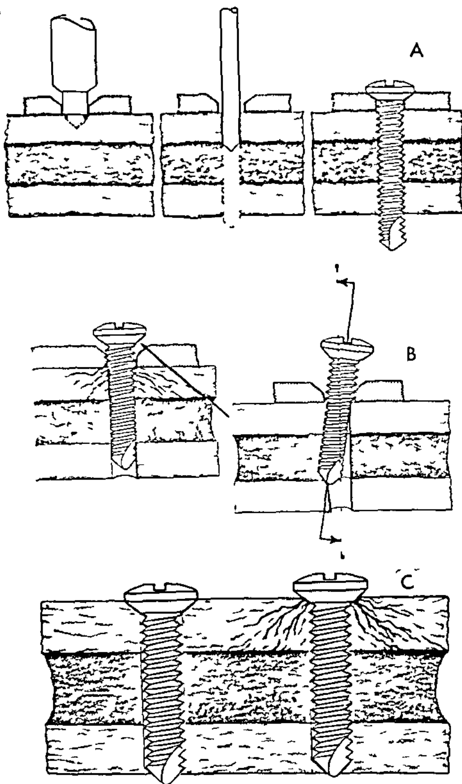


Fig 8 (A) A drill guide is e ential for properly centering the screw hole in relation to a bone plate in order to secure maximum fixation from the crew With the hole properly centered the screw will properly contersink into the plate with evenly distributed pressure (B) The eccentrically drilled crew hole (left) damage the metal thread in contact with the plate Angulation of the crew (right) as it is placed in the screw hole damages threads and cau es lateral migration of the crew with resultant damage to the bone threads already cut (C) When the crew alone is used to fix the fracture it should be counter unk to avoid either prostru ion or exce sive strain and splitting of the bone or tearing out of the bone thread (From Peter on L T Principles of internal fixation with plates and screws Arch Surg 64 345 1952)

1 Tantalum an element with a tough oxide coat

2 Type 302 stainless steel consisting of 17 to 19 per cent chromium and 8 to 10 per cent nickel "It must be annealed before use at 1800°F to prevent intergranular corrosion and be passivated in 20 per cent nitric acid to insure a good protective coat of oxide"

3 Type 316 stainless steel containing 16 to 18 per cent chromium, 10 to 14 per cent nickel and 2 to 3 per cent molybdenum It should be annealed at 2000°F

4 Vitallium a cobalt alloy with 30 per cent chromium and 3 per cent molybdenum

Plates and screws were placed in the unfractured bones of 26 dogs and in the fractured bones of 10 more dogs The implants were removed after three months There were microscopic particles of metal embedded in the tissue around this plate screw junction of virtually all the specimens The fragments were larger and more abundant in the tantalum and type 302 steel preparation than around type 316 steel Those around vitallium were fine crystals that could be seen only with polarized light The only visible corrosion was at the plate screw junction An unfavorable tissue reaction was accompanied by visible corrosion and an increased number of free metallic particles In only 6 of 72 specimens was there an unfavorable reaction around more than one plate screw junction in any single plate The incidence of unfavorable metal tissue reactions was 30 per cent for tantalum, 30 per cent for type 302 steel, 10 per cent for type 316 steel, and 0 for vitallium

Titanium was investigated by Jergesen[9] and a report published in 1954 Screws and plates containing more than 99 6 per cent elemental titanium were used The surface hardness was 27 to 35 on a Rockwell C scale There was no evidence of bone necrosis or delayed osteotomy healing in the experimental animal Approximately one third of the experiments revealed a limited discoloration of the tissues in the region of the screwheads Spectrographic microchemical, and microscopic determination seemed to reveal that the cause was iron in a few instances and in others was minute titanium fillings Bone grew in the threads of the screws and holes of the plates and the metal appeared to be well protected by the tissues There was some evidence of weakness of the screws when a torque such as would be used in their removal was used

Leventhal[30] also demonstrated the relative inertness of titanium by implanting it into the subcutaneous tissue of rabbits and the femora of rats Bone blocking about the screws was so firm that difficulty was experienced in removing some of them The question of strength of the metal in this design was not answered Wakanatsu noted the strong at

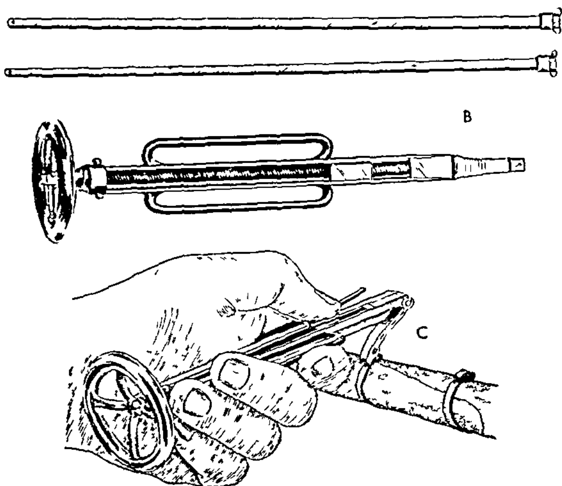


Fig 9 (B) Putti's band and tightener (C) Tightening the band or bone with Putti's apparatus

and plate, and drill and saw and bone This has significance as delineating another cause of corrosion and metal failure

It is worth remarking that particle size may have quite an effect on the reaction of tissue to metal A finished plate with an oxide coat may be quite inert However, in powdered form the activity of the metal may be increased, titanium and zirconium becoming so liable to rapid oxidation as to be nearing the explosive stage Skin reaction to metals in powdered form has been reported Shelby and Hurley[37] have written on the development of allergic granuloma from zirconium deodorant

There is now widespread interest in establishing standards and specifications for metallic implants Interest in the field is still spurred by incidences of metal failure or tissue reaction The numerous new alloys developed in the atomic age are waiting to be tested Metal has had an opportunity to act on human tissue for over 90 years The reaction of tissues to this chronic exposure is just beginning to become evident A

tachment of bone to metal in his experiments with titanium The reaction of the bone marrow reminded the author of chemical injury However, the metal was produced by the magnesium reduction method and was probably not free from impurities

In the field of neurosurgery some interest was expressed in tantalum This apparently was an outgrowth of the substitution of tantalum for silver in the tiny clips used for hemostasis by Cushing Bailey and his associates[31] noted the tendency for a fibrous capsule with giant cells in the stroma to form about aggregates of tantalum powder Hawkins[3] reported on the use of braided tantalum wire as a suture after finding an incision hernia in 9 of 136 patients and noting sepsis in 11 Koontz and Kimberly[33] noted that fibrosis was extensive with the use of tantalum mesh, which was apparently interpreted as an advantage Mirowsky and his associates[34] reported 11 cases in which an epidural granuloma formed about a tantalum plate with or without an abcess, which necessitated removal of the plate The use of tantalum for cranial plates has largely been taken over by plastic compounds

Very sound mechanics have been emphasized by Peterson[3] who found that disproportion between drill size and screw diameter was one of the most serious sources of error Obviously the size of the threads of screws and the size of drills and screws as a unit should conform to exactingly accurate standards In order to avoid one cause of loosening and fatigue failure of screws plates should be curved transversely with the radius of curvature less than the radius of the bone Rocking motion of the plate is thus prevented as its edges engage the bone The use of a drill guide was recommended by this author as well as taking care to prevent unequal tightening of the screws which might cause each to break in turn

Bowden Williamson and Laing[6] have recorded that bits of metal from the screwdriver are transferred to the screw in the process of insertion This metal transfer also occurs between hammer and nail drill

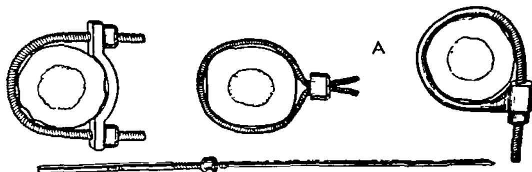


Fig 9 The derivation of Parham Bands (A) Professor Lambotte s wire loops bolted against the bone

3 Lister J Brit M J 2 8?? 1883
4 Venable C S and Stuck W G The Internal Fixation of Fracture Charles C Thoma Springfield Illinois 1947
5 Zierold A A Reaction of bone to various metal Arch Surg 9 365 1924
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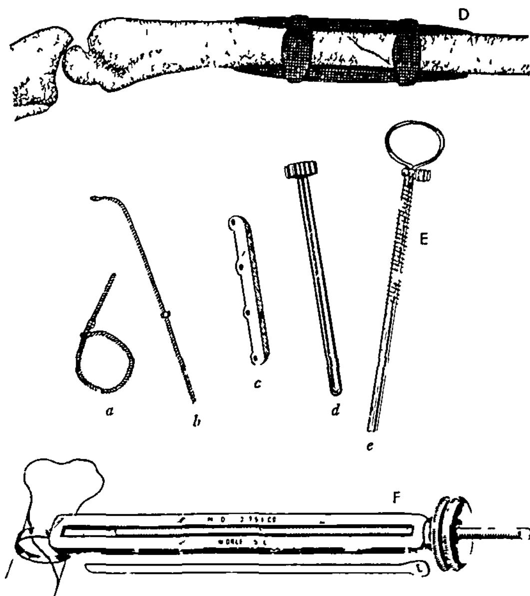


Fig 9 (D) Putti s bands holding two plates in place (E) Milne s instrument for holding metal band with screw thread along its entire length (F) Parham s band with loop at one end and instrument for snagging free end through loop (From Parham F W Circular constriction in the treatment of fractures of the long bone Surg Gynec & Obst 23 541 1916)

thought expressed by Key 20 years ago still holds that if internal fixation is not absolutely necessary for the successful treatment of the case it probably should not be used

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2

METAL BEHAVIOR: THE CORROSION PROCESS

Albert B Ferguson, Jr , M D

Most metals, far from being static, durable materials, have been purified above the form found in nature Their natural tendency is to revert to the lower form by oxidation This reversion is called corrosion A thorough knowledge of the corrosion process will bring every surgeon into a general routine in the handling of metals in living tissue that will help to eliminate the occasional failure That dissimilar metals will cause corrosion by setting up a battery effect seems generally known in surgery This is largely because of the attention drawn to this effect by Venable and Stuck in 1937 Less well known is the fact that two pieces of a similar metal may corrode, or that a single piece of metal may corrode—all for different reasons, but still as much a part of success and failure of the operation as the more obvious "dissimilar metals "

It is believed that it will eventually be possible for good judgment (backed by a ground work of corrosion knowledge) to distinguish the fact that there is no one perfect metal The metal used should be determined in part by the type of stress to be placed upon it and the expected duration of its stay in the tissues Some features that are very important over the long haul fade into relative insignificance when a mere six weeks insertion is envisaged

There are three basic problems to be met in using metals in the tissues

1 *Electrolytic inflammation* Corroding metal may set up a typical tissue reaction In a severe form this may be accompanied by rejection of the implant In a mild form it may play a part in failure of bone repair and be evidenced clinically by thickening and tenderness of the overlying tissues

2 *Stress tolerance* The metal must meet by design and composition the expected stresses to be imposed upon it or metal failure might ensue This becomes quite complicated as repeated stresses in a corrosive environment may cause it to fail well below its calculated safe limit



Fig 10 A 30 year old vanadium steel plate and a screw On removal the metal resembled a part of a sunken ship with little to no structural integrity The plate consisted of little more than rust

3 *Using an uncontaminated implant* The metal must be brought to the operating table under the best possible conditions for its use with success, uncontaminated by organisms other metals, or damaged surfaces and with no new stresses or design changes brought into its structure since its manufacture It goes without saying that its manufacturer must have complied with a code of the highest order when the implant is to be used in the human being

The Corrosion Process

Corrosion is an electrochemical process It requires a solution of electrolytes such as is readily available with any aqueous medium There follows the setting up of an anodic area Here electrons are released and metal ions formed by oxidation and disintegration of the metal This is the area where actual disintegration takes place *i e*, where pitting, blemishing and the deterioration of the surface appears Here ions of metal pass into solution A cathodic area must exist in relation to the anode with the way open for a negatively charged electron to pass from the anodic area to it A means of connection or the contact of the metals is enough to permit this The anode and cathode may exist on the same piece of metal These areas of potential difference may change in location allowing visible corrosion to be seen all over the metal surface This state may be set up on the metal with the speed of light upon immersion in an aqueous medium

At the cathode area the positively charged ions in the solution may (as in the case of water) be met and neutralized by the electron exchange and hydrogen gas formed Negatively charged hydroxyl ions are left

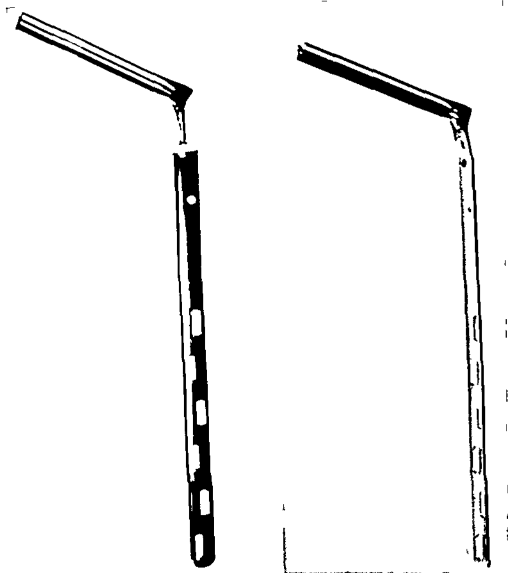


FIG 11 Excessively long plate and nail combination broken at junction of the long lever arm formed by the plate with the first screw hole below the nail

increasing the alkalinity of the area There are then two types of areas, the one at which metal dissolves and the one at which hydrogen ions are discharged or consumed by oxygen

If the interface between a metal and its environment is entirely homogeneous these areas of potential difference would not exist In order to be set up for a corrosion cell certain areas on the metal surface must be chemically or physically different from the rest Differences in strain, crystalline structure oxide and metallic impurities on the surface may all lead to differences in solution tendencies The more homogeneous the surface caused by special preparation the more resistant will it be to disintegration The environment must also be homogeneous A lesser

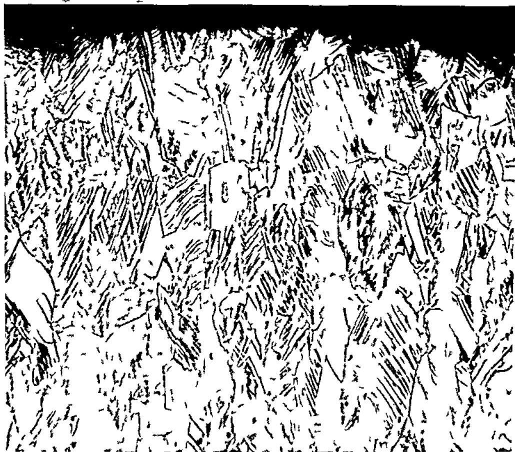


FIG 12 This is the surface of a stainless steel screw that corroded through at the edge uppermost in this photograph Stress lines show as linear markings in the structure of this piece of worked metal The surface of the metal is visualized microscopically by reflected light

tendency for corrosion of certain metals in acid is presumably the result of homogeneity of the metal acid interface

In summary the anode corrodes (oxidizes) in a solution containing electrolytes with a cathode in relation to it There is a passage of electrons between the two The anodic and cathodic areas of potential difference may change as ions accumulate in one area

What speeds or accelerates the process? What slows it? And what practical cause or means of setting up this process can be avoided?

ENVIRONMENT

One of the first important understandings to be gained of corrosion as a process is that each environment has its own action on a metal Another way of saying this is to note that strong resistance to a chloride solution does not imply equally strong resistance to a solution of a strong acid As a general statement metals in use in the human body are noted

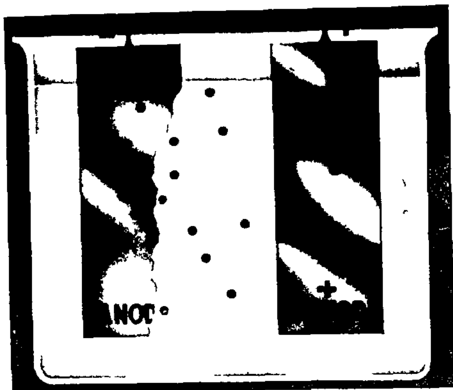


Fig 13 The flow of electricity between anode and cathode Note that disintegration takes place at the anode The metals are immersed in a solution of electrolytes (Courtesy International Nickel Company)

Fig 14 The ordinary dry cell illustrates the principles of corrosion The cathode is graphite the anode is the zinc covering Ions are supplied by ammonium cloride When a wire connect cathode with anode there is a flow of electricity (Courtesy International Nickel Company)

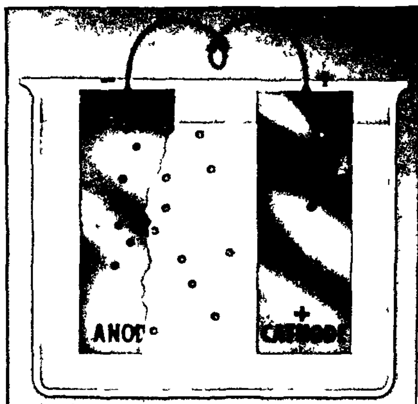


Fig 15 With two different metal plates a wire is necessary to form a metallic path be tween them in order to complete the circuit and allow for the flow of electrons in a corrosion cell (Courtesy International Nickel Company)

for their corrosion resistance in an aqueous medium containing chloride ions The environment of the human body is a unique situation the atmosphere has been completely excluded banishing nitrogen among other things Oxygen is brought to this environment and continually replenished and there is a flow of chloride ions through it The circulation of ions is rapid through an aqueous medium The area is under alternating strains resulting in internal stresses in the metallic implant

THE TISSUES ABOUT IMPLANTS

By spectrographic analysis it is possible to show that all metals currently in use as implant materials in the human body give off ions to the surrounding tissues The easiest example and one that can be grossly demonstrated is the presence of iron An iron stain of the tissues about an appliance that is removed will readily serve to convince the skeptical The effect of these ions on physiological processes such as calcification is a matter of conjecture That some ions may embark from the alloy in a concentration relatively higher than that in which they exist in the

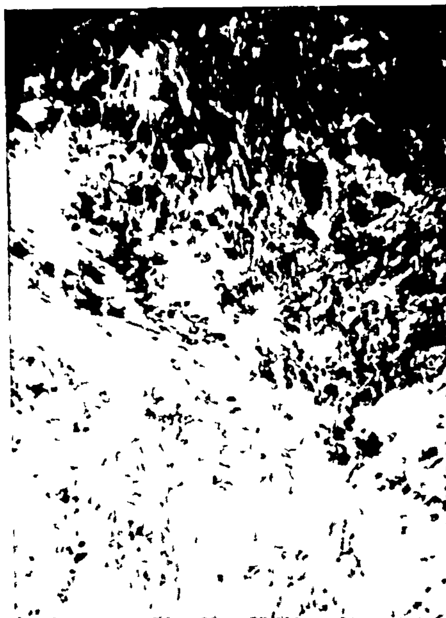


Fig 16 Iron deposited in the tissues is easily demonstrated by a Prussian blue stain The collections of metal in the tissues are seen as the amorphous black granules

appliance has also been noted This may result in a change in composition of the embedded alloy

Spectrographic analysis also reveals that many of the constituents making up the commonly used alloys are present in a very small concentration in normal tissues

The crucial level at which the concentration of these ions reaches the point of causing clinical changes is not known The familiar clinical example however, is the long dormant area about an embedded bone

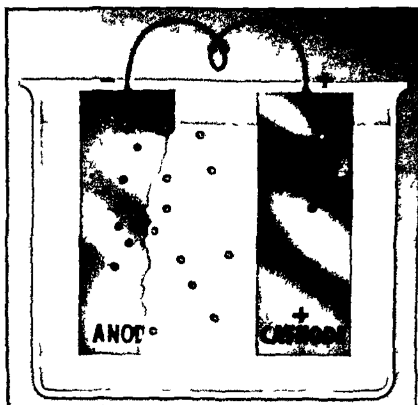


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TABLE 1

Electromotive Force Series The Action of Metal in Particular Concentration of Its Own Salt

*Hydrogen is taken as zero and other metal rated in relation to it The metals are im*mersed in a solution of their own salt When coupled one with another the one higher up in an electromotive force series table will suffer accelerated corrosion

Metal	Standard Electrode Potential
	25 C
Increasingly reactive	
K	−2 922
Ca	−2 87
Na	−2 71
Mg	−2 34
Be	−1 70
Al	−1 67
Mn	−1 05
Zn	−0 762
Cr	−0 71
Ga	−0 52
Fe	−0 440
Cd	−0 402
In	−0 340
Ta	−0 336
Co	−0 277
Ni	−0 250
Sn	−0 136
Pb	−0 126
Arbitrary reference	
H_2	0 000
Cu^{++}	0 345
Cu^{+}	0 522
2Hg	0 799
Ag	0 800
Pd	0 83
Hg	0 854
Increasingly inert	
Pt	*ca* 1 2
Au^{++}	1 42
Au^{+}	1 68

series of metals and alloys in sea water (Table 2) Here again the metal near the top of the table will suffer accelerated corrosion and be anodic in relation to the metal below it in the table with which it is coupled There are some interesting things about this galvanic series table Note that the much used 316 steel in an active state is high up on the table After passivation it hastens to the bottom of the table in a position much less likely to suffer accelerated corrosion This table comes closer to predicting the action of an alloy in a human tissue environment, but still is only a relative rating

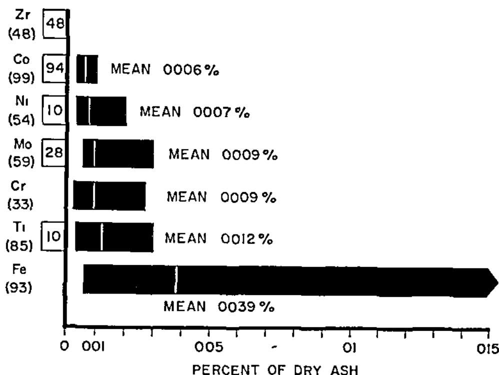


FIG 17 Chart of the results of spectrographic analysis of skeletal muscle in rabbits The number under each element symbol is the number of samples analyzed The black bar represents the range of results the white line the mean The flags are the number in which none was found *Note that most elements composing corrosion alloys are present to some degree in normal tissues*

plate which suddenly after years of implantation flares with an acute, aseptic inflammation

CORROSION CURRENTS

Dissimilar metals when coupled together in an electrolyte have potential differences The corrosion resulting is known as galvanic action Local action is the corrosion occurring from point to point on the same metal The latter corrosion may be caused by surface imperfections, structural differences or environmental differences Metals when immersed in a solution of their own salt have a potential rating in relation to hydrogen which is taken as zero When these metals are coupled, one with another the one higher up in an electromotive force series table (Table 1) will suffer accelerated corrosion Note that these are single metals not alloys and that the metals may have a different potential rating when combined in an alloy

A useful study of expected galvanic action is obtained from a galvanic

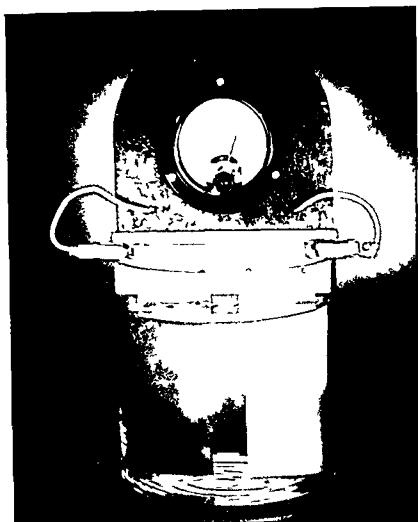


FIG 18 The dial registers a potential difference of 700 mv between passive stainless steel (left) and carbon steel (right) in solution of warm sulfuric acid (Courtesy International Nickel Company)

oxygen It can be shown experimentally that an electric current will flow between points where oxygen concentration differs

On a single metal surface different concentrations of metal ions may set up because of varying conditions An example from industry is the whirling disc which corrodes at its periphery where the metal ions are swept away as compared to its center where they accumulate The corrosion is most severe at the area of highest velocity of the whirling disc It should be recalled that in the human body oxygen is brought to the tissue and ions swirl past a given area with considerable speed It is not a static environment

Clark and Hickmann[1] have attempted to develop an *in vitro* test to determine which metals might be useful in a living tissue environment

TABLE 2

Galvanic Series of Metals and Alloys in Sea Water

The metals and alloys have had their action recorded while immersed in sea water. The metal nearest the top of the table will be the anode in relation to those below it and will suffer accelerated corrosion.

Magnesium	Red brass
Zinc	Copper
Alclad 3S	Aluminum bronze
Aluminum 61S	Composition G bronze
Aluminum 63S	90-10 Copper-Nickel
Aluminum 52	70-30 Copper-Nickel-low iron
Low steel	70-30 Copper-Nickel-high iron
Alloy steel	Nickel
Cast iron	Inconel
Type 410 (active)	Silver
Type 430 (active)	Type 410 (passive)
Type 304 (active)	Type 430 (passive)
Type 316 (active)	Type 304 (passive)
Ni-resist	Type 316 (passive)
Muntz metal	Monel
Yellow brass	Hastelloy
Admiralty brass	Titanium
Aluminum brass	

The speed of galvanic corrosion will be affected by the degree of potential difference between two metals. If a metal is next to the metal just below it in the series table the potential difference will be very slight and the process of corrosion very slow.

Diffusion and corrosion of metal ions from about an anode may be relatively slow despite the great speed with which metal ions dissolve and hydrogen ions are discharged. This accummulation of ions resulting in a difference of solution tendency is known as anode polarization.

There may be a polarization at the cathode caused by the accumulation (for example) of hydrogen gas. This effectively covers the cathodic surface and removes it from an active part in the corrosion process. The cathodic area receives galvanic protection. It should be recalled that a cathode, an anode, an electrolyte, and a means of passage of electrons are still necessary for corrosion to take place. When the cathodic area becomes unavailable the process stops.

The availability of the cathode will be affected by its size in relation to the anode and by the concentration of ions affecting the polarization. If these ions are spread thinly over a large cathode the polarization will be relatively ineffective and the corrosion process will still proceed.

The available oxygen will affect the oxidation process, since the speed of progression will depend on its rate of flow and concentration over the area. Cathodes will develop at areas of high oxygen concentration or

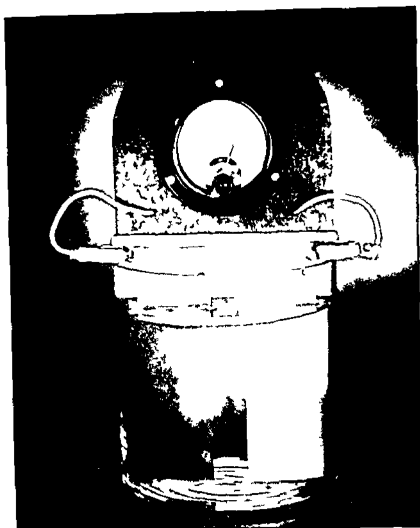


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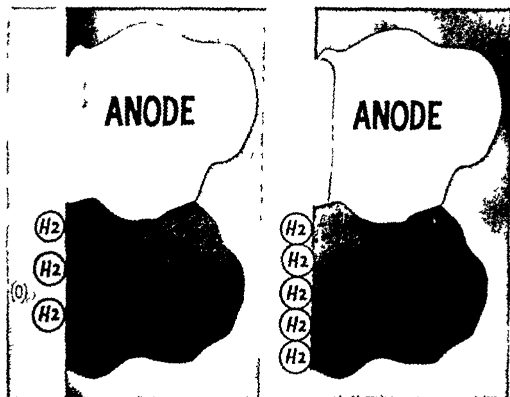


FIG 19 (*left*) The polarization of a local cathode by the accumulation of hydrogen The hydrogen covers the cathode and removes it from active participation in the corrosion process bring the process to a halt (Courtesy International Nickel Company)

FIG 20 (*right*) Depolarization of the cathode by the removal of hydrogen by oxygen in the solution The accumulation of hydrogen stops the corrosion process since the film of hydrogen isolates the cathode from the process Both oxide and cathode are necessary for corrosion to occur (Courtesy International Nickel Company)

They used a rotating rod with the test metal as the anode, a calomel electrode as the cathode and measured the potential drop for a known current across an electrolytic cell in a bath of equine serum The internal resistance drop was subtracted and a measurement termed the anodic back electromotive force was obtained This appeared to have a rough correlation with the action in physiological fluid Those metals which had negative potentials appeared to be more reactive than those having a positive potential The correlation is indeed of a general nature only and intended only to classify roughly those metals which might have a future in insert use

OXIDE FILMS OR OXYGEN LAYERS

Many metals owe their corrosion resistance to a marked tendency to unite with oxygen at the surface forming a film which is nearly impervious to future passage of oxygen atoms There are ways of increasing this

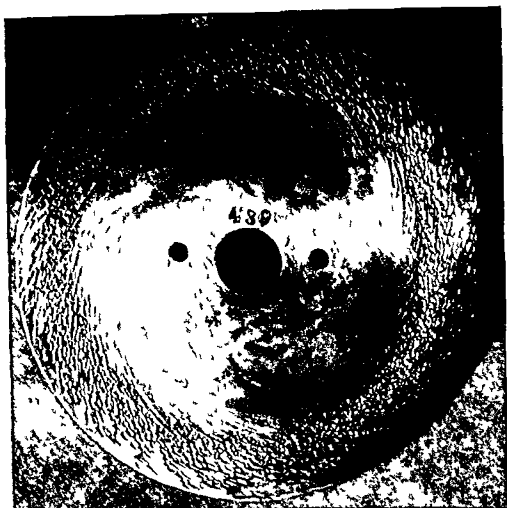


FIG 21 This brass disc which has been rapidly rotated in sea water has suffered corrosion at the periphery Here ions have not been allowed to accumulate because of the high velocity at the edge This has allowed corrosion to continue without a deceleration in rate (Courtesy of International Nickel Company)

surface tendency to unite with oxygen This is true of aluminum Stainless steels owe their corrosion resistance to passivity, a condition of negligible corrosion despite a chemical tendency to combine with the metals' environment A strongly oxidizing condition increases the resistance to attack Thus with salt solutions freely exposed to air a stainless steel by surface oxidation can remain relatively inert in a corrosion sense A sealed stagnant solution may find its original oxygen used up, whereupon pitting attack of the steel becomes possible Under certain circumstances a high local concentration of carbon dioxide combined with oxygen may cause rapid corrosion

STRESS AND STRAIN

A stress or force applied to a metal may produce a strain or deformation When the stress is small the deformation is elastic in character

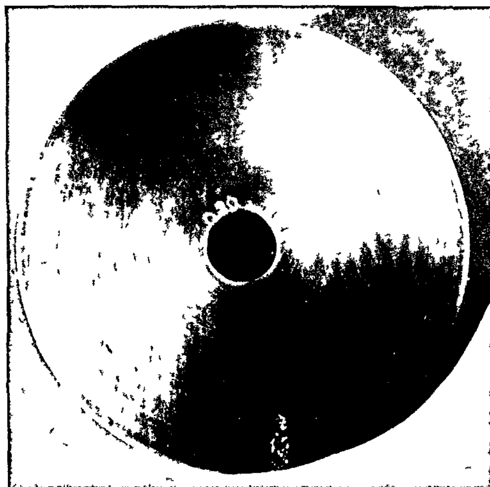


Fig 22 A monel disc after rotation in sea water showing a complete lack of velocity attack The right type of metal for the environment and function was used (Courtesy International Nickel Company)

TABLE 3

Anodic Lack Electromotive Force

Those metals rating +400 or over were rated as being in the range where they could be considered for inert use

Tantalum	+1650
Platinum	+1450
Gold	+1000
Vitallium	+650
Stainless steel (18 8 S mo)	+480
Silver	+110
Copper	+30
Mild steel	−480
Zinc	−9[illegible]0
Magnesium	−1550



FIG 23 There is visible corrosion beneath the pile of sand on this brass plate Here oxygen was relatively excluded resulting in an area of low oxygen potential (anode) with an area of relatively high oxygen potential (cathode) about it (Courtesy International Nickel Company)

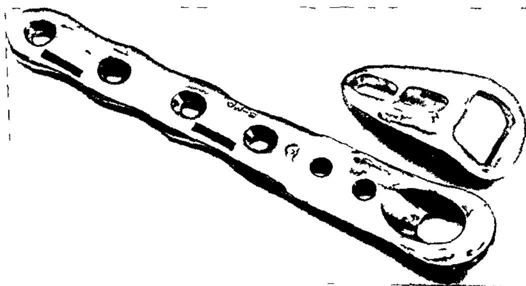


FIG 24 Note the visible corrosion occurring where the plate and the device for holding the hip nail were in contact The area on the device is a mirror image of the area on the plate Here oxygen was relatively excluded



Fig 25 The addition of nitric acid to a warm sulfuric acid solution acts to passify the active stainless specimen As a result there i a reduction in existing potential between active and passive stainless steel Here the dial registers less than 100 mv i reduction from the potential before passivation (Courtesy International Nickel Company)

When the stress is removed the metallic implant returns to its original form When the stress exceeds the elastic limit a permanent or plastic deformation is produced and the implant no longer returns to its original shape The effect of the stress will vary in different portions of the metal, some areas permanently deformed others still retaining elastic tension, and in attempting to spring back putting other areas under tension A worked piece of metal contains a balance of tensional and compressional stresses no further change in shape then occurs Tensional stresses often



Fig 26 A bent plate has had a stress or force applied to it to produce a strain or deformation The shape that remains is a balance of tensional and compressional stresses and no further change in shape occurs Note that a stress corrosion crack has started on the far side of the central screw hole at the point of maximal bend the crack in the fine line extending into the top of the highlight area at the screw hole

and intergranular corrosion A corrosive solution which can exert a preferential action on intergranular matter will show up such areas in a very practical way Such a method exists in police work for bringing out automobile engine numbers on stolen cars even though they have been previously erased Acid is applied to the area where the previously stamped numbers have been erased This attacks the areas of unrelieved internal stress beneath the stamped area, bringing the numbers back into view

When alternating and repeated stresses occur as in the human body (which is a corrosive environment) the most susceptible areas may be not the intergranular boundaries but disorganized areas along slip planes It is possible for alternating stress to crack and implant in a corrosive environment This is usually because of a highly localized attack Such an implant may crack well within the safe stress ranges determined under noncorrosive conditions

Intense local attack is termed pitting corrosion Corrosion concentrated at a small area may produce great damage so far as function of the metallic implant is concerned A cracked bone plate has lost its structural value despite its failure to corrode elsewhere

MECHANISM OF STRESS CORROSION CRACKING

Stress corrosion is a term that is limited to cases *in which there is* no significant corrosion damage in the absence of stress The mechanism of

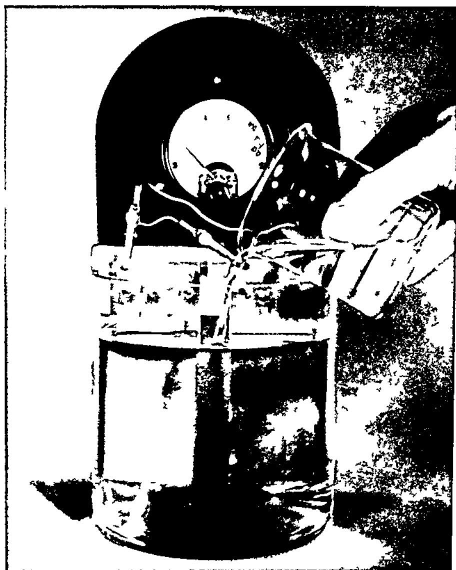


FIG 25 The addition of nitric acid to a warm sulfuric acid solution acts to passify the active stainless specimen As a result there is a reduction in existing potential between active and passive stainless steel Here the dial registers less than 100 mv a reduction from the potential before passivation (Courtesy International Nickel Company)

When the stress is removed the metallic implant returns to its original form When the stress exceeds the elastic limit a permanent or plastic deformation is produced and the implant no longer returns to its original shape The effect of the stress will vary in different portions of the metal, some areas permanently deformed others still retaining elastic tension, and in attempting to spring back putting other areas under tension A worked piece of metal contains a balance of tensional and compressional stresses no further change in shape then occurs Tensional stresses often

Causes of Corrosion in the Human Body

From corrosion as a general phenomenon it is possible to draw specific causes which are quite relevant to understanding phenomena that occur when metals are embedded in living tissue It is not intended to discuss fully all the causes of corrosion but only those that in particular seem important when metal is used in this way

MIXED METALS

Venable, Stuck, and, later, Key have emphasized the fact that alloys of widely varying composition when linked together in an electrolytic medium have a potential difference that aids the physiochemical phenomenon known as corrosion The classic example is the use in combination of vitallium (a cobalt based alloy) and stainless steel (an iron based alloy)

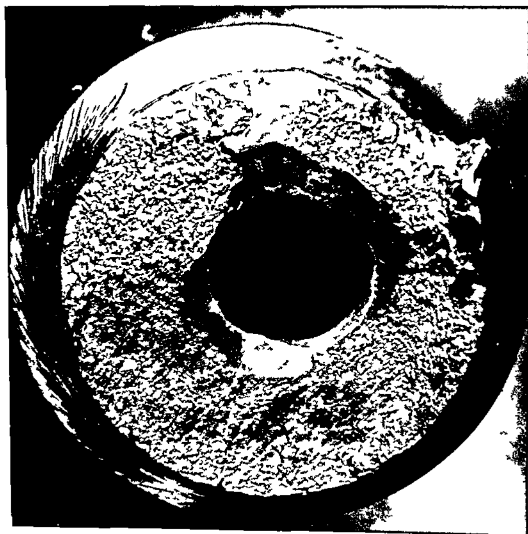


Fig 28 The corroded end of a hip immobilizing device which failed The smooth areas at top and bottom of the central canal are caused by wear between the two fragments

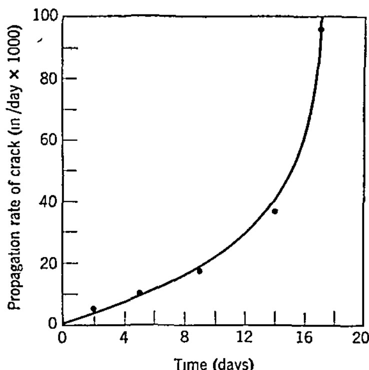


Fig 27 The propagation rate of a stress corrosion crack Note the acceleration in rate with increased time The diagram was drawn from data obtained from an aluminum 7 per cent magnesium alloy (From Gilbert P T and Hadden S E J Metals 77 237 1950)

failure caused by stress corrosion cracking has been described by Dix and his associates in a symposium

They note that there is a concentration of stress at the base of a localized corroded path The stress concentration increases with deepening of the attack and leads eventually to tearing apart of the metal Dix and his associates wrote "Since it has been observed that a scratched metal surface is anodic to an unscratched metal surface the tearing action described would expose fresh metal unprotected by films to the action of a corrosive environment

Stresses and deformation can rupture films and promote localized and accelerated corrosion but according to Harwood[3] there is insignificant evidence that this phenomenon is a major factor in crack propagation

It is clear that variations in processing and composition have affected the microstructure of metal and made it more susceptible to stress corrosion cracking The structure of the metal influences the point of initial localized attack as well as the path an attack takes and its rate of progression

A stress corrosion crack may be either intergranular or transgranular as it cuts across the metal, but tends to grow in a plane perpendicular to the tensile stress on the appliance

ing, and fabricating the implant. Since residual surface or subsurface tensile stress must be present for this phenomenon to occur, at least those stresses which have unavoidably occurred in manufacture should be relieved by heat or appropriate treatment before being released for human consumption. The design may favor the development of stress corrosion phenomenon since some devices are notched and stamped, and so on.

TISSUE CHANGES WITH INJURY

There is a pH change occurring in damaged tissue which has been brought out by Murray and Swenson. A potential difference between injured and normal tissue has been recorded. It is apparent that following necrosis and tissue injury there is a pH fall to 5.3 to 5.6. A gradual rise ensues with the development of a pH close to 7.35 in approximately ten days. The exudation of blood products in varying stages of decomposition is usually extensive and is accompanied in the early stages by an acute inflammation. There is a rapid growth of blood vessels into the area. It has been felt by some metallurgists that these changes represent a much more corrosive environment than formerly suspected for some metals. It brings up the point once again that living tissue is a unique environment in the corrosion field.

DIFFERENTIAL ELECTROLYTIC GRADIENT

Any differences in the concentration of ions in contact with different parts of the same metal surface may induce corrosion currents.

DIFFERENTIAL OXYGENATION

When two metal appliances of exactly the same type suffer corrosion in a surgical case it may be the source of consternation to the surgeon

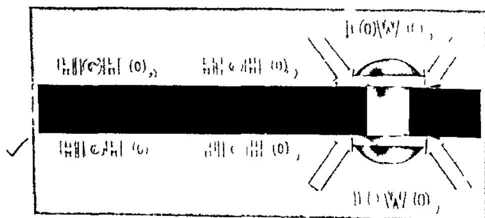


FIG. 30. A plate and bolt showing active and passive areas on stainless steel with oxygen shielding leading to the active condition. (Courtesy International Nickel Company.)

This mixture is all to prone to occur if the devices to be used for implant are not carefully separated in hospital operating rooms Less well known is the fact that varying hardnesses and variations in crystalline structure in the same alloy may also set up potential differences

STRESS CORROSION CRACKING

The methods of reducing the susceptibility to stress corrosion cracking appear to include careful attention to the method of designing, assembly



Fig 29 A stress corrosion crack with intergranular corrosion extending from the surface of the metal

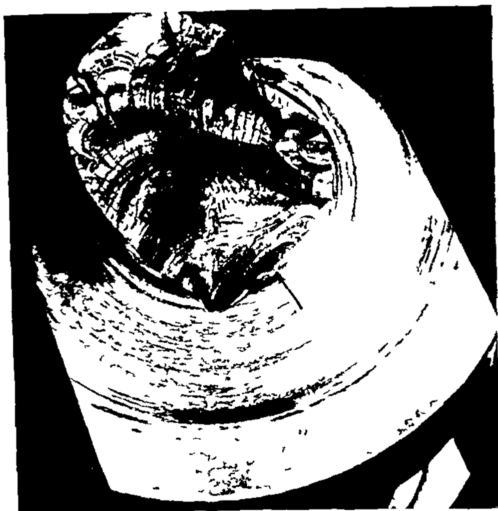


FIG 31 This end of view of a service fatigue fracture shows the characteristic oyster shell marking very well This occurred in the steel shaft of a punch press (From Grove H J Gordon S A and Jackson L R Fatigue of Metals and Structures Bureau of Aeronautics Department of the Navy)

number of repetitions of stress rather than mere duration of time Modern speed has put a big burden on design in order to avoid repeated stresses caused by fatigue failure Such a situation particularly holds true in aircraft No metal in the usual implant design will stand up to the stresses put upon it by walking in the presence of nonunion of the bone Weight bearing on an ununited fracture will soon cause cracking of the plate

The service fatigue fracture on the surface of the fracture part shows some distinctive areas that enable the fracture to be recognized as caused by fatigue

1 There is a crescent shaped area with a ground or rubbed appearance spreading out from the initial nucleus This area sometimes has concentric oyster shell markings

2 About this area is a region of more jagged surface texture which

An instance of this type may be explained by the fact that where the two metal implants were in close contact oxygen was excluded causing an area of low oxygen potential (the anode) Around it was an area of relatively high oxygen potential (the cathode) Such a form of corrosion may be seen at the interface where two intermedullary rods cross and are opposed to each other or under the screw head, where it was in contact with the plate The area around the screw eyes is frequently where staining of the tissues is noted The corrosion often initiates in this area because of the oxygen differentials It is principally reduced to acceptable levels by the design of the appliance

METAL TRANSFER

The use of tools of one alloy may result in transfer of bits of thin alloy to an implant of a different composition The early use of stainless steel sheeting on modern buildings gave rise to an example of the importance of this phenomenon, for corrosion occurred where it had been tapped in place by tools of a different composition This particular cause is more fully treated separately

SURFACE DEFECTS

It has already been brought out that a scratch on the metal surface is anodic in a corrosive environment to the metal surface about it Such an area when stress is also brought to bear upon the implant may be conducive to metal failure by cracking There may be precipitates or impurities on the surface The path of such corrosion in stainless steel, for example is a zone depleted in chromium as a result of the local precipitation of carbides In general a great deal of attention must be paid to surface finish to render an implant as corrosion resistant as possible Damaging the surface by such means as stamping manufacturer s names or size numbers would appear to be an unnecessary procedure, lowering the quality of the implant

Many metals depend for their corrosion resistance in an aqueous chloride containing medium on an oxide surface layer Damage of such a layer might have an opportunity to heal itself but this may not be true when the atmosphere is excluded as within the body Damage to such surface oxide layers may open the surface to attack when the size of penetration is greater than the critical self healing size beyond which pitting may occur

FATIGUE

Although fatigue is generally thought of as a function of time it has been shown by the experiment of Woehler and others that it is the

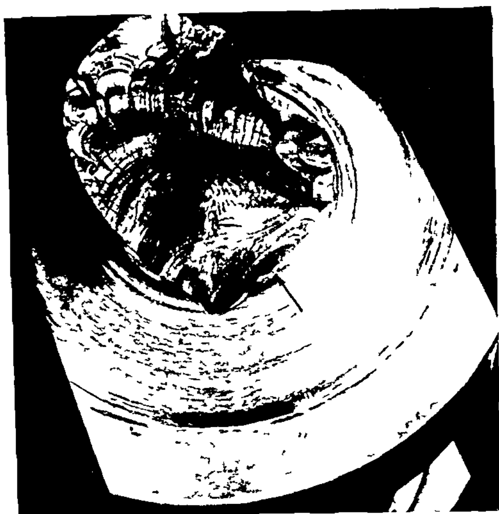


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2 About this area is a region of more jagged surface texture which

represents a final tensile fracture after the initial crack had weakened the implant

The presence of the oyster shell markings is a good indication of fatigue failure although they do not always occur In general, the larger the area of the initial smooth crescent the lower the stress level This may not be truly discerned, however, if there is more than one nidus of stress Diagnosis on the basis of appearance alone may be impossible

Metal fatigue seems to depend on the number of repetitions of a given stress rather than upon the total time it bears the load Some alloys appear to have a fatigue limit Below a certain stress amplitude failure does not occur even after an enormous number of cycles of stress Notches, grooves and defects of a physical type appear to greatly decrease the ability of the implant to withstand a given number of cycles of stressing The achieving of failure in an implant in a fixed number of cycles occurs



FIG 32 It is expecting a great deal of any design suitable for insert use to stand up to a nonunion Here a fatigue fracture of the immobilizing screw has occurred in this ununited femoral neck fracture

with a decreased range of stress as the mean tension stress of the loading cycle is increased

Fatigue cracks start at a nucleus of stress and progress without causing large scale deformation. There is, however, microscopic evidence of deformation in the region of the crack. These cracks in general follow the line of least resistance in the metal and usually cross grain boundaries. They start not only at points of faults and inclusions, but will tend to progress from one fault to another should they exist.

Since ability to withstand fatigue failure cannot be correlated with other common engineering properties and since it occurs in a highly localized region it is necessary to go to other knowledge gained in other ways in order to guard by design against this cause of implant failure.

This knowledge is often gained by tests of specific materials, specific design, method of fabrication, and information about service loads. Frequently a model or prototype of the design is tested.

Fatigue is a very practical problem in the life of hip prostheses. The average, adult male in a sedentary occupation walks 10 to 15 miles a day and in the process puts each foot on the ground 1000 times a mile. During the course of a year this adds up to over 3 million impulses each of several hundred pounds per square inch to each femoral head.

VARIATIONS IN HARDNESS

Hardness is usually defined as the resistance of a metal to indentation. There are a number of methods of testing hardness. The test method used gives a measure of the metal's resistance of this type of trauma only. It is necessary to know the method used when it is stated that a metal has a certain hardness. The numbers used as a designation are empirical only. In the Brinell test a steel ball is carried into the test metal by a

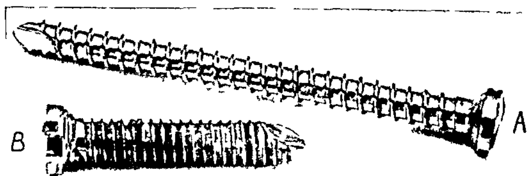


FIG 33 Screws from two different manufacturers used together in the same case. Note one screw (A) the longer is bright and shiny presumably the cathode. At (B) the short crew corrosion is visible in the form of pitting all over the screw with actual destruction and cracking just beneath the head.

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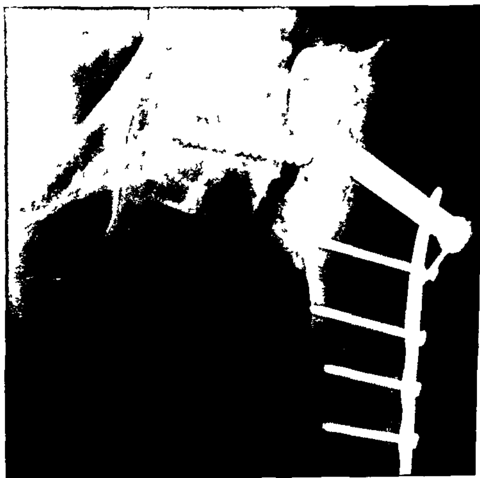


Fig 32 It is expecting a great deal of any design suitable for insert use to stand up to a nonunion Here a fatigue fracture of the immobilizing screw has occurred in this ununited femoral neck fracture

metal should be removed or left buried in the human body The reader should now be aware of the fact that metal is not a fixed static material but one which is actively changing in relation to environment

Time is a factor in this change Thus if the life expectancy is great, removal of the metal appliance would definitely be indicated It is obvious that any metal placed in the bone in childhood ought to come out The reaction to the metal may seal off the medullary canal to such an extent that the growth rate of the bone is changed from the normal The process of disintegration having many years to run stands a good chance of saturating the tissues to the point of sudden acute inflammation There are unknowns in the action of these ions which when finally delineated may give still stronger reasons for metal removal

The aged, on the other hand, with short life expectancy, may not have sufficient clinical justification to remove the metal when the hazards of the procedure are evaluated

Discomfort is a reason for removal Many metal appliances placed about the joints have bursae which form about the prominent end moving through the tissues Pressure against the bursa over the prominent end of the hip pin in the region of the greater trochanter while lying down is often sufficient to cause the patient to complain and wish it alleviated

Each case should be individually evaluated, but in general when life expectancy is great or the metal of such a size as to interfere with function it should be removed

REFERENCES

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2 Grove H J Gordon S A and Jackson L R Fatigue of Metals and Structures pp 1–2 Bureau of Aeronautics Department of Navy 1954

3 Harwood J J Corrosion 6 249 1950

4 Robertson W D Stress Corrosion Cracking and Embrittlement John Wiley and Sons, New York 1956

5 Brick R M and Phillips A Structure and Properties of Alloys McGraw Hill Book Company Inc New York 1949

6 Zapffe C A Human body fluids affect stainless steel Metal Progress July 95 1955

7 Bain L C Functions of the Alloying Elements in Steel p 66 American Society for Metals Cleveland 1939

8 Corrosion in Action International Nickel Company 1955

known load, the measurement of the diameter of the impression is converted by a formula into a Brinell hardness number In the Rockwell test the depth of penetration of a steel ball or diamond core of a certain diameter is automatically indicated on a dial There are many variables in these tests which are beyond the scope of this volume It is sufficient to note that metals may have different hardnesses although of the same composition, and this may result in metal failure by bringing together surfaces having different characteristics The hardness is to some extent related to the grain size in stainless steels, and three quarters hard steel should have a grain size of 6 or 7 for best performance

Tensile Test

A metal machined to a specific shape may be subjected to an axial load tending to stretch the metal The amount of stretch (deformation or strain) when correlated with the stress applied will give engineering specifications of the metal The elastic limit is the maximum stress to which a metal may be subjected without suffering some permanent deformation The yield point is found when plastic deformation starts to progress without increasing the load

The Question of Metal Removal

It is fitting to discuss at the conclusion of this chapter on the electro chemical and physical characteristics of metal the question of whether

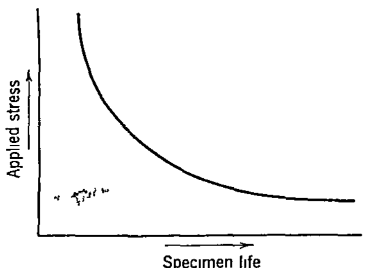


Fig 34 Applied stress has a relation to specimen life which has been diagrammed here by J J Harwood The greater the magnitude of applied stress the shorter the time to failure It should be noted that the relation is to the number of instances of applied stress rather than merely to their duration (From Robertson W D Stress Corrosion Cracking and Embrittlement John Wiley and Sons New York 1956)

The first group has yielded two promising candidates, titanium and zirconium, and one disappointing one, tantalum

One may conveniently subdivide alloys into groups designated by the major base element contained in them

1 *Iron based alloys* For our purposes our interest centers on the American Iron and Steel Institute 316 and 317 stainless steels, but may come to include such new alloys as A286 and 17 7 pH stainless steel

2 *Cobalt based alloys* Two members of this group are in use for the manufacture of implants and are very popular

3 *Titanium based alloys* Many of these alloys may prove interesting to surgeons eventually and are under active investigation

4 *Nickel based alloys* As yet these have only been used as implants experimentally, although some have attractive properties

5 *Aluminum based alloys* These have inferior corrosion resistance in the body and are not a practical proposition

6 *Others*

At this stage in our knowledge we can limit ourselves to three of these groups (Fig 35) (1) the stainless steels, (2) the cobalt-based alloys, and (3) the commercially pure elements

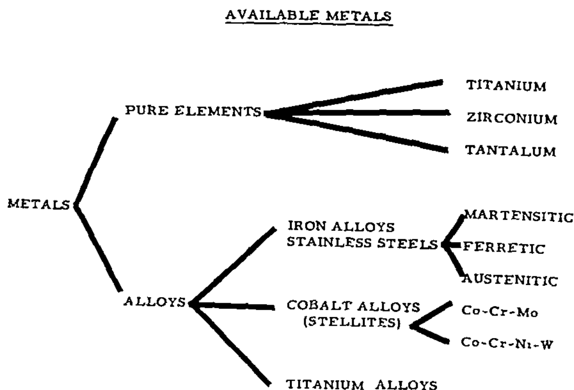


Fig 35 The family tree of the metals discussed in this chapter is shown here The cobalt alloys are represented by the chemical symbols for their constituent elements The titanium alloys are included as they seem likely to prove of interest in the near future

3

AVAILABLE METALS

Patrick G Laing, M D

In this chapter an attempt will be made to survey the whole field of metals in relation to their use as surgical implants It is probably true that the surgeon should know as much about a metal he implants in a human being as he would expect to know about the hormone or drug tablet he was asked to implant for therapeutic reasons

There is a very large number of metals available for our use today More and more alloys are being developed by the metallurgists to meet the demands of the Space Age In particular many strong metals able to operate at high temperatures in rocket and jet engines have been found to possess truly remarkable corrosion resistant properties at lower temperatures

Four main factors have to be considered in the choice of a metal for implanting in the body The first of these is that the metal must be strong enough to do the mechanical job required of it The second is that it shall be able to resist corrosion by the body fluids to which it will be exposed during the implant s expected length of stay in the body It is of little use to make a bone plate out of a highly corrosion resistant material which is so brittle that it snaps at the first strain to which it is exposed Conversely, a really strong metal which has little ability to resist corrosion in the wet chloride environment in the tissue is obviously a poor choice Third, the metal should not be too expensive or in short supply Fourth, it should be capable of being machined forged, or cast without too much difficulty

When one surveys the entire range of metal many groups may be dis tinguished some of which are of little interest to us at the moment, but may later become important

The metals may first be divided into

1 Commercially pure elements with no deliberately added alloying elements

2 The alloys where several elements are combined to give one metal

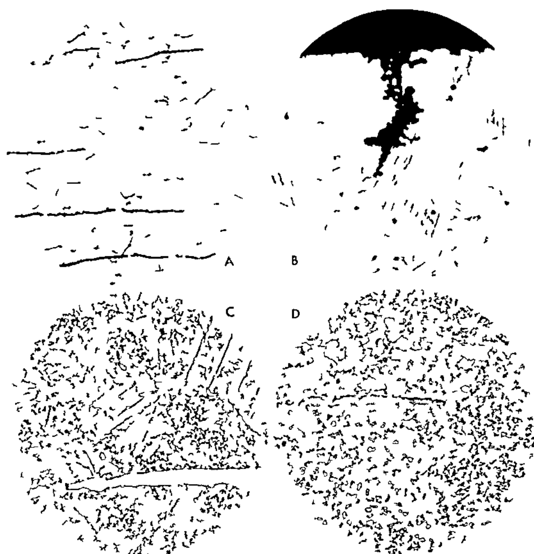


Fig 37 Four typical microphotographs of metal prepared as described in Figure 1 All show inclusions in the steel which are undesirable in implants (A) The thin dark lines seen are probably sulfide inclusion These are the often deliberately produced in the so called free machining steel They provide easy lines of cleavage for the cutting tool but adversely effect the corrosion resistance (B) A lead inclusion is seen penetrating the surface of a steel bar This surface defect forms a good site for corrosion to start (C) The large inclusion seen here is probably manganese (D) Another large inclusion which may be a silicon particle (Microphotographs by courtesy of Universal Cyclops Corp)

by producing planes of cleavage They may be lead inclusions since lead is sometimes used to lubricate metal during manufacture of wire Carbide inclusions may be present because of precipitation of carbides from solution in iron Silicon inclusions may occur accidentally during melting

Each metal also has a characteristic crystalline structure at the molecular level and this will be described when dealing with each one in turn (Fig 38)

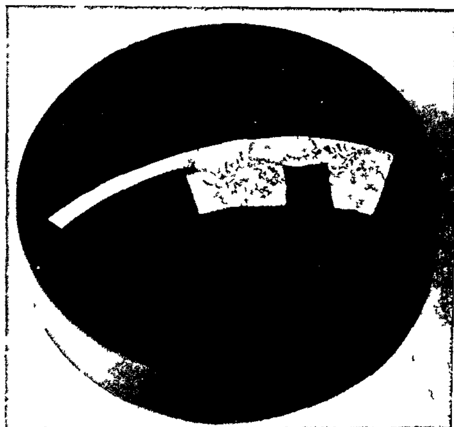


Fig 36 This photograph shows a typical metallurgical specimen consisting of the metal to be examined under the metallurgical microscope embedded in plastic The metal is highly polished and then etched This specimen is actually cut from the head of a femoral replacement prosthesis which shows a welded junction between two halves of a globe

Before going on to deal in detail with each one of these groups of metals and for the benefit of people with little knowledge of metallurgy, it is necessary to say a few words about the internal structure of metals All metals have a characteristic crystalline structure when viewed under the metallurgist s reflecting light microscope In order to demonstrate the internal structure of a metal it has to be especially prepared just as a tissue section has to be stained This preparation consists of preparing a highly polished flat surface of the metal embedded in a plastic holder (Fig 36) This surface is then etched with some corrosive agent or by electrolytic attack This etching attacks the grain boundaries of the metal surface outlining the individual crystals and demonstrating the grain size and internal characteristics of the metal sample Faults in its structure and such things as corrosion cracks may be seen One may find for instance inclusions of various elements either accidentally or deliberately inserted (Fig 37) These may be sulfides in a steel to aid free machining

about 2802°F, it becomes solid and is said to "freeze." It is now called ferrite or delta iron and has a characteristic crystalline structure known as "body centered cubic." With further cooling this structure changes to a more compact "face centered cubic" structure known as austenite or gamma iron at 2552°F. The differences between these two molecular structures are shown in Figure 38. When the temperature drops to 1671°F a further change occurs and alpha iron with a body centered cubic structure is formed and is identical with delta iron. A slight expansion takes place during this last change. These changes are shown diagrammatically in the constitutional diagram for iron (Fig. 39). Under certain circumstances a third structure is found called martensite. Here the atoms have been trapped in a distorted or strained position during their change back from austenite to ferrite.

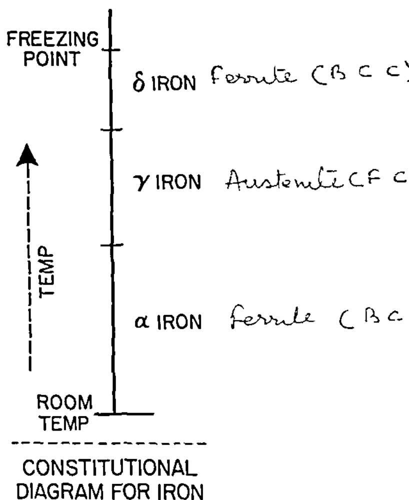


FIG. 39. As molten iron cools it first freezes or solidifies as delta iron or ferrite with a body-centered cubic (B C C) structure, then on further cooling converts first to gamma iron or austenite with a face centered cubic (F C C) structure and then back to B C C now known as alpha iron.

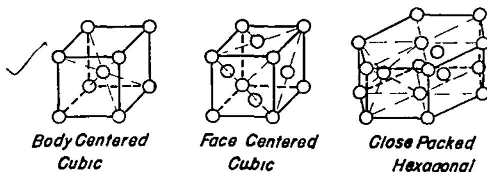


FIG 38 The three typical atomic arrangements in metal crystals are shown here They will be referred to often in the text in discussing the characteristics of various metals Most of the metals we are interested in are allotropic i e have two possible arrangements (From Schwartz H A Foundry Science Sir Isaac Pitman & Sons London 1950)

TABLE 4

Chemical Composition of Some Stainless Steels

	C	Ni	Cr	Mo	Fe
	per cent	per cent	per cent	per cent	per cent
AISI 316					
Typical (a)	0 06	13 4	17 8	2 3	64
Typical (b)	0 08	11 7	17 5	2 5	66
AISI	0 1 max	10 to 14	16 to 18	2 to 3	Bal
AISI 317					
Typical	0 07	13 32	18 96	3 3	62
AISI	0 1 max	11 to 14	18 to 20	3 to 4	Bal
18 8 S Mo (British)	0 07	8 0	18 0	2 75	70

STAINLESS STEEL*

Stainless steel is a blanket term covering a large number of alloys all having an iron base It is necessary to be much more specific before one can understand what particular stainless steel we are interested in It is a difficult term to define Steel, very roughly speaking, is a solution of carbon and iron Stainlessness is achieved by adding of various elements, each of which confer specific properties on the iron The first and most important of these elements is chromium After this comes nickel and then other elements including molybdenum The specifications for some stainless steels are given in Table 4

Constitution of Iron

Iron exists in two main forms alpha and delta iron which are identical, and gamma iron It is said to be allotropic When molten iron cools to

* Much of the basic information contained in this section is well presented in 'Stainless Steels by Carl A Zapffe published by the American Society for Metals Cleveland Ohio 1949

about 2802°F, it becomes solid and is said to "freeze." It is now called ferrite or delta iron and has a characteristic crystalline structure known as "body centered cubic." With further cooling this structure changes to a more compact "face centered cubic" structure known as austenite or gamma iron at 2552°F. The differences between these two molecular structures are shown in Figure 38. When the temperature drops to 1671°F a further change occurs and alpha iron with a body centered cubic structure is formed, and is identical with delta iron. A slight expansion takes place during this last change. These changes are shown diagrammatically in the constitutional diagram for iron (Fig. 39). Under certain circumstances a third structure is found called martensite. Here the atoms have been trapped in a distorted or strained position during their change back from austenite to ferrite.

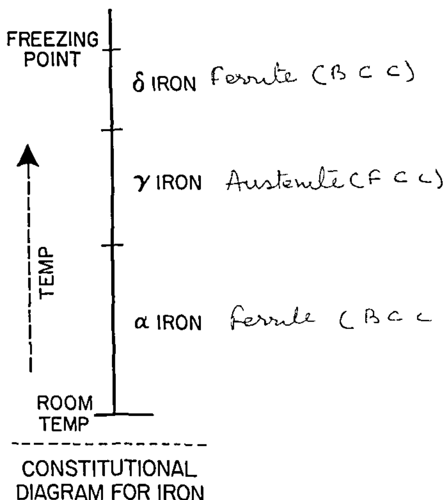


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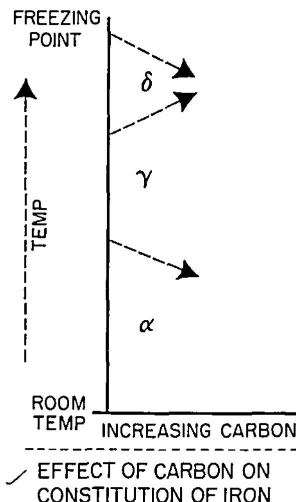


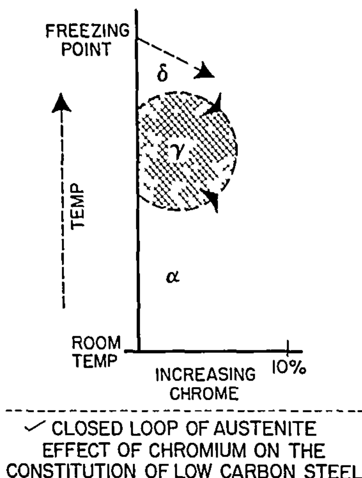
FIG 40 The addition of carbon in small quantities lowers the freezing point of molten iron elevates the point of conversion from B C C to F C C and depresses the point of return to the B C C structure It thus widens the austenitic range

Effect of Carbon

The addition of increasing amounts of carbon to iron lowers the freezing point raises the temperature at which austenite appears and lowers the temperature at which it reverts to ferrite These changes are shown diagrammatically in Figure 40

Effects of Chromium

Chromium is an intensely corrosion resistant element and is freely soluble in iron to which it gives some of this highly desirable corrosion resistance Chromium has the property of first expanding the austenite range or gamma iron and then in higher concentration of decreasing this range This gives the closed gamma loop Over a concentration of 12 per



CLOSED LOOP OF AUSTENITE
EFFECT OF CHROMIUM ON THE CONSTITUTION OF LOW CARBON STEEL

Fig 41 Here the effect of adding chromium is shown With increasing chrome the point of change from B C C to F C C is raised then lowered Conversely the point of change back to B C C is lowered then raised until the austenite range is a closed loop It gives from highly desirable corrosion resistance & strength cent chromium austenite disappears from chromium steel leaving only ferrite These changes are detailed in Figure 41

Effects of Nickel and Other Elements

Another element, nickel,[1] has the important property of widening the austenitic range until, when added to chrome steel in concentrations over 10 per cent nickel the austenitic structure becomes stable at room temperature It is thus known as a loop opener as it expands the austenite range (Fig 42) Increases in the amount of nickel tend to lower the tensile strength and hardness and decrease the tendency to harden with cold work Nickel being an austenizer, allows the addition of more chromium and also molybdenum, both with desirable strength and corrosion resistant properties Like molybdenum and chromium, tungsten, vanadium, columbium, titanium and zirconium are also ferritizers

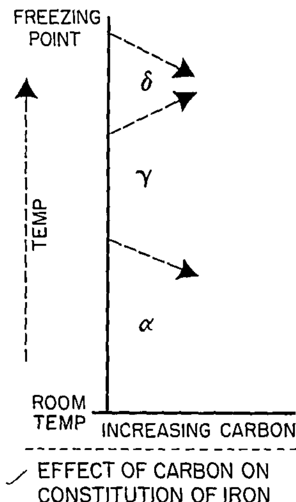


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Class II Stainless Steels Ferritic Steels

This class has a chromium content of 16 per cent up to 46 per cent These steels are permanently ferritic and have superior corrosion resistance but poor strength except in the lowest chromium range where they overlap Class I and have some hardenable characteristics They are like Class I steels attracted by a magnet

Class III Austenitic Steels

In these steels chromium ranges from 16 to 26 per cent nickel is added to stabilize the austenite until in concentrations over 5 to 7 per cent, austenite becomes the major structure at room temperature (Fig 40) Some of these steels however have some slight ability to transform to martensite under the mechanical pressure of being "worked" and are thus slightly work hardenable With concentrations of nickel over 10 to 12 per cent this work hardenability goes and we get the 18 8 stainless steels i e about 18 to 20 per cent chromium and about 8 per cent nickel, usually 10 to 14% By adding molybdenum a ferritizer, in quantities up to 2 per cent we get the American Iron and Steel Institute (A I S I) type 316, ad up to 3 5 per cent molybdenum gives type 317 These last two stainless steels have superior performance in the presence of the chloride ion and thus in sea water[3] and in the human body They obtain this property mainly from the molybdenum They are nonmagnetizable

Character of A I S I 316 and 317

These two alloys unfortunately usually A I S I 316 and not the superior 317 are in common use for the manufacture of surgical implants So-called 18 8 S Mo stainless steel in Europe has a lower nickel content than A I S I types 316 and 317 i e , 8 per cent rather than 10 to 14 per cent Probably a higher nitrogen concentration[4] is used as an austenizer in place of the expensive and rare nickel A I S I 316 and 317 stainless steels have borne the test of time commendably in the field of surgical implants (Fig 43) However they now have many competitors produced by the developing science of metallurgy to meet the rigorous conditions operating inside jet and rocket engines These new alloys and elements often have suitable strength and passivity to interest the surgeon

STRENGTH

A I S I 316 and 317 stainless steels are very strong and as far as this goes their performance is satisfactory In the fully annealed or fully soft condition A I S I 316 has an ultimate tensile strength of about 80 000 pounds per square inch (p s i), and a yield strength of 35,000 p s i for

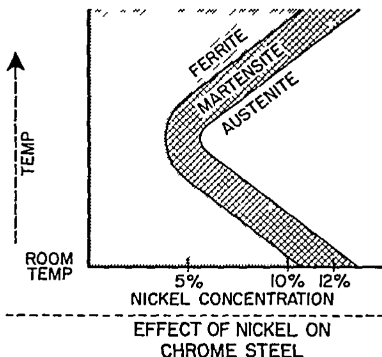


FIG 42 When nickel is added to chrome steel beyond the range of the closed loop it reintroduces the austenitic structure (F C C) with higher concentrations of nickel austenite becomes stable at room temperature There is an intermediate range however when on cooling austenite partially reverts to ferrite giving the hard martensitic steels

Allows addition of more chromium & Mo

Molybdenum[2] has great resistance to attack by chlorides and to pitting corrosion and it gives these properties to steels to which it is added

The Importance of Austenite

Why is it important whether steel is austenitic or ferritic? This is explained by Zapffe who divided the stainless steels into three main classes and then examined the properties of each In general, ferrites have good corrosion resistant properties whereas austenites have superior corrosion resistance and good strength

Class I Stainless Steels Martensitic Steels

These steels contain 12 to 18 per cent of chromium and are hardenable By this it is meant that on heating they pass from ferritic to austenitic structure but fail to convert completely back to ferrite on cooling under prescribed conditions The strained hard structure is martensitic The hardness increases with increasing carbon content for the carbon "traps" the moving atoms and produces a strained structure These steels are very strong indeed but have limited corrosion resistance They are attracted by a magnet

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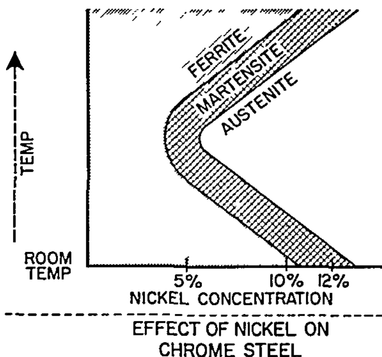


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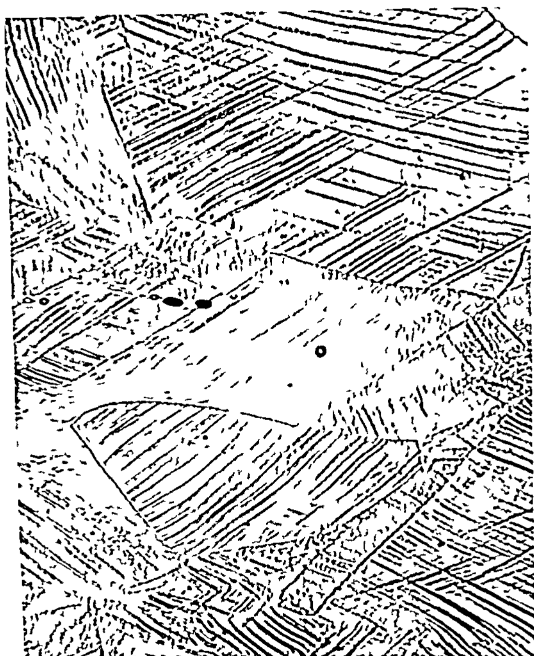


FIG 43 (B) Here the same steel is shown in the worked condition with many etched lines of internal strain crossing the grains (Microphotographs by courtesy of Crucible Research and Development Laboratory)

so marked in the 316 and 317 range as it is in the rest of the group but five ranges of hardness are usually available to manufacturers These are (1) fully soft or annealed (2) quarter hard (3) half hard, (4) three quarters hard (5) fully hard

Manufacturers of surgical implants usually use three quarters hard A I S I 316 which on hardness testing on the Rockwell machine gives a value of 28 to 35 on the C scale This test has A B, and C scales with an



Fig 43 (A) This highly magnified metallurgical microphotograph shows the etched crystal boundaries of a fully annealed or dead soft stainless steel Note the smooth grain surfaces

0 002 per inch strain In the work hardened and forged state their strength is greatly increased up to a maximum of 200 000 to 350 000 p s i

HARDNESS

Stainless steels may be hardened by cold reduction in size by plastic deformation of their internal crystalline structure This is not however

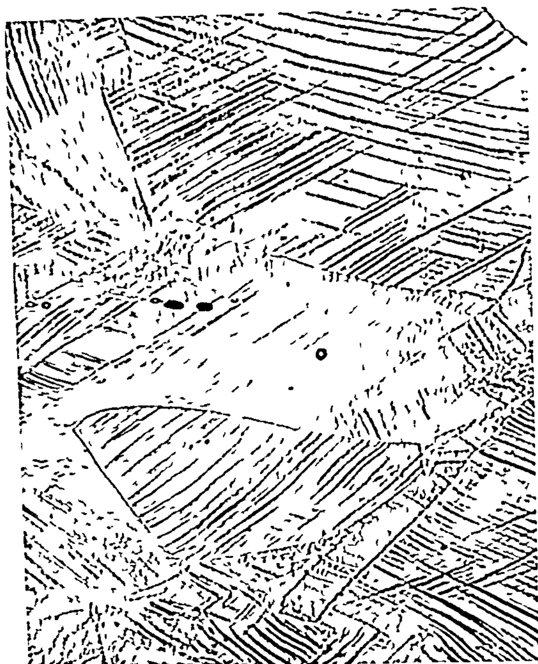


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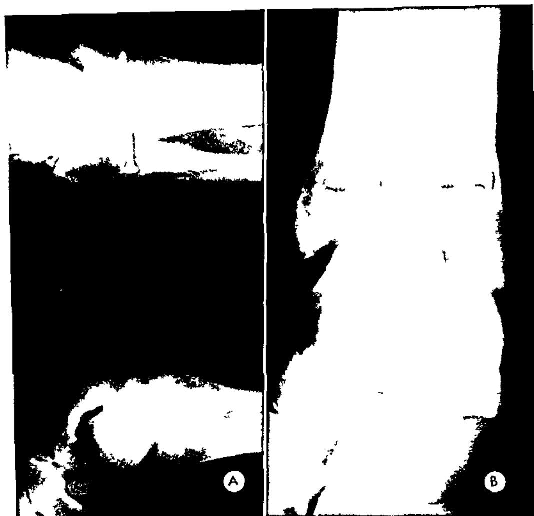


FIG 44 (A) Antero posterior and lateral radiographs of a fractured ankle with screw fixation of diastasis of the inferior tibio fibular joint A zone of bone resorption surrounds the part of the screw embedded in the fibula (B) The screw has failed by fracture This could well be an example of stress corrosion cracking Constant movement between the tibia and fibula in a corrosive medium provides the ideal situation for such an occurrence

trate the oxide film and provide zones for corrosion to start This aspect will be enlarged upon in a later chapter

SUSCEPTIBILITY TO DIFFERENTIAL OXYGENATION

A I S I 316 and 317 stainless steels are also susceptible to differential oxygenation and pitting corrosion is likely to take place whenever there is one part of the implant in contact with a high oxygen environment and another part in contact with a low one[6] (Fig 45) On a plated fractured bone there is likely to be a low oxygen tension between screw and plate where metals touch The rest of the metal, if it is in contact with living tissues will have a high oxygen environment It has been explained in a

increasing load applied to the indenting point from A to C. As far as the corrosion properties go it is advisable that all parts of all implants should have the same hardness as well as the same composition or else they will behave as different metals. This is not always the case in surgical implants comprising several parts. It may be more convenient for the manufacturer to make a nail out of three quarter hardness and the rest out of dead soft alloy. From our point of view, this is probably poor practice.

GRAIN SIZE

The actual grain size also has an important bearing on the performance of A.I.S.I. 316 and 317 steels. The grain is talked about as a number from one to eight with larger numbers meaning a decreasing size of grain. A grain size of six to seven is usually recommended for the manufacture of surgical implants and this small grain seems to have an important part in resisting corrosion cracking.

CORROSION RESISTANCE

The corrosion resistance of A.I.S.I. 316 and 317 stainless steels is very satisfactory under most conditions.[5] Of the two, type 317 is definitely superior for our purposes. Neither, however, can be unreservedly recommended for very long term performance in a chloride solution such as the body. In particular they are liable to stress corrosion cracking if the exposed surface is under tension in a corrosive medium for a long time (Fig. 44). Unfortunately, the addition of other alloying elements has little value in reducing stress corrosion cracking. Apart from faulty engineering of implants this susceptibility to stress corrosion cracking is probably the main reason for failure by fracture of A.I.S.I. 316 and 317.

SUSCEPTIBILITY TO SURFACE DAMAGE

As has been explained previously, the corrosion resistance of the stainless steels seems to depend on their ability to form a protective layer of oxides on their surfaces. The exact nature of the surface sludge or film is debatable. It may be merely a molecular layer of oxygen or it may be a quite thick layer of oxides, i.e., a few Ångstroms in depth. However, the ability of the steel to reform or heal this surface layer after damage is critical to its corrosion resistance.[5] Also, if the surface damage goes deeper and deforms the crystalline structure underneath, it is possible that some transformation of austenite may occur with undesirable effects on the corrosion resistance. These steels must remain absolutely undamaged if they are to exhibit their best corrosion resistance.

The dangers of metallic transfer during storage and their insertion into the body are very great. Small pieces of metal transferred from tools pene

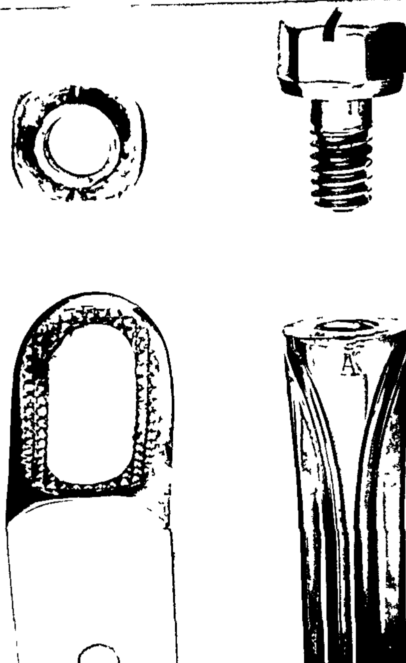


FIG 45 The four parts of this intertrochanteric appliance have corroded where they touched each other Several factors may have precipitated this corrosion The lowered oxygen tension at the metal to metal interfaces as compared to the high oxygen tension present where vascular tissue is the neighbor may have produced differential aeration The metal parts may have been in differing metallurgical states or even have had different compositions

previous chapter how this may lead to corrosion by setting up corrosion currents between the two zones

One agent which may slow pitting corrosion on these steels is the polarization of the cathodic areas thus slowing down the passage of electrons

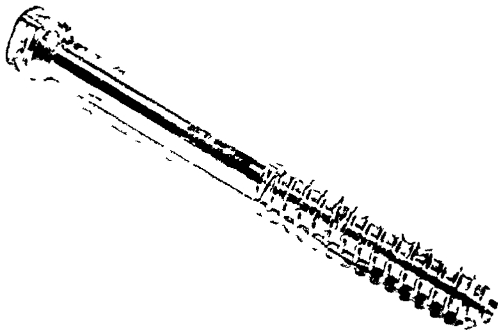


FIG. 44 (C) Here a Lorenzo screw has failed by fracture at the site of the last screw thread. This is a typical example of what may be stress corrosion cracking caused by overstressing of the implant in a corrosive environment. (Photograph by Crucible Steel Research and Development Laboratory.)



FIG. 44 The right of this highly magnified microphotograph of steel shows quite a small surface defect. The whole metal structure underneath, however, is disintegrating. Practically nothing untoward may be visible on the surface until quite suddenly fracture occurs. (Microphotograph by Crucible Steel Research and Development Laboratory.)

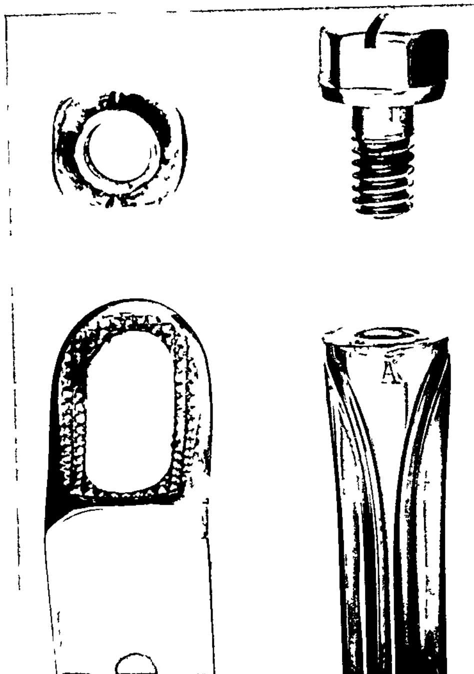


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from anode to cathode However, oxygen in a stagnant solution will depolarize the cathodic area and promote pitting at the anode Other oxidizing agents, such as chromates have the opposite effect of preventing this depassification and thus slowing down the corrosion

VARIATIONS OF ANALYSIS WITHIN SPECIFICATIONS

There is another difficulty in using these types A I S I 316 and 317 or any alloy prepared on a large scale Different melts from the same steel mill may have slightly different compositions Key[7] has shown the inherent dangers of this in practice Mixing implants made of steels obtained from different sources introduces the chance of inserting mixed metals There is quite a wide range of chromium nickel and molybdenum content allowed within the specifications of the A I S I for these two types (Table 4) For instance, in type 316 the chromium may vary between 17 and 20 per cent and the nickel between 10 and 14 per cent Preferred practice demands an alloy with high values of both elements but this is not always the case in every melt

The advantages of A I S I 317 and 316 are many (1) they are reasonably cheap (2) they are easily machined or forged (3) they are freely available from many steel mills, (4) they are strong and (5) they are very corrosion resistant (Fig 46)

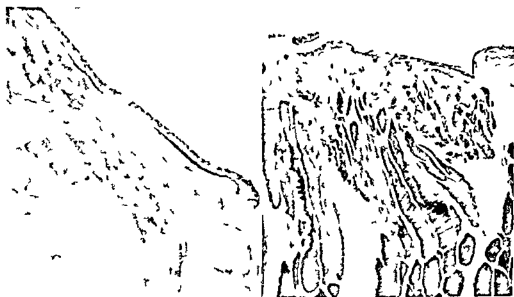


Fig 46 These two photomicrographs show tissues which had been in contact with A I S I 316 stainless steel for several months These tissue reactions are typical when no obvious corrosion is present (A *left*) This tissue is very vascular and several parallel layers of fibroblasts align at what was the metal tissue interface The dark lines below this layer consists of iron salt shown up by the Prussian blue reaction (× 120) (B *right*) Muscle fibers are here seen separated from the metal tissue interface by a layer of fibrous tissue some capillaries and a layer of a few cells thick of parallel fibroblasts (× 360)

This last is true only provided they are not overstrained in a corrosive environment and that the implant is well engineered The design is often of critical importance in the strength of these implants, because crevice corrosion is an ever present danger [8]

Their disadvantages include (1) their dependency on a highly polished, undamaged surface for their corrosion resistance, (2) they are especially susceptible to metallic transfer at all stages of their lives (3) in addition, these steels have only limited corrosion resistance in a wet chloride environment, and (4) high concentrations of the elements of the alloy can be found in tissues around the implants

This last point is probably especially true if at any time there is a drop in pH Uhlig has shown[9] that apart from the severe corrosion below pH 2 8 the deepest pits in 316 steel occur at pH of 6 to 7 in 4 per cent sodium chloride These steels for instance, are seldom recommended unreservedly for service in sea water The body extracellular fluid may prove to be an even more severe test of their inertness than sea water

Spectrochemical analysis of tissues adjacent to implants of 316 and 317 stainless steel show the presence of relatively large amounts of their main constituent elements [10] The possible significance of these trace metals on tissue metabolism is unknown Oppenheimer and his associates[11] have shown that both A I S I 316 and cobalt chrome molybdenum implants in rats may be carcinogenic In addition, the effect of trace metals on bone salt nucleation and the calcification process in general is unknown

With some reservations, one can thus recommend these strong, corrosion resistant steels for use as implants, the main reservation being that the implant must be well taken care of A limited stay in the body is probably to be desired, and until the whole picture becomes clearer the removal of such implants when they have done their work is desirable They are thus probably not to be recommended for the manufacture of implants which must stay in the body for many decades

Cobalt based Alloys

Cobalt with an atomic number of 27 occurs in the periodic table in Group VIII between iron and nickel Like iron, cobalt is allotropic, *i e*, exists in two main crystalline forms Alpha cobalt is stable at room temperatures and has a close packed hexagonal form which is very regular When cobalt is heated it changes to a face centered cubic structure which it apparently maintains to the melting point The austenitic range for cobalt starts when it solidifies but goes before the temperature falls to room levels [1] Raudebaugh[13] compares the transformation from beta to alpha cobalt on cooling with martensite formation in iron There are two alloys of interest to us cobalt chromium molybdenum and cobalt chromium nickel tungsten

Another alloy cobalt-chromium nickel molybdenum iron has been used for implants It has wonderful corrosion resistance and resistance to stress corrosion in an oiled medium, but, according to unpublished work, seems to have poor corrosion resistance in living tissues and it will not be further discussed here

The Stellites

Early this century it was found that the addition of chromium to cobalt produced a very remarkable alloy [14] Chromium is readily soluble in cobalt and the original alloy contained 25 per cent chromium and 75 per cent cobalt It was named stellite, being a star among metals and this name has become generic for a large group of cobalt based alloys

In general, carbon has an effect on cobalt rather similar to that on iron, and the cobalt alloys we are concerned with have significant amounts of carbon Cobalt alloys in fact may be divided into high carbon alloys and low carbon alloys and the latter group are used for the manufacture of implants

As far as the main alloying elements are concerned Badger and Kroft[15] state that chromium molybdenum and tungsten raise the temperature at which beta cobalt changes to alpha cobalt, whereas iron and nickel depress this temperature In general, these alloys consist of a cobalt rich solid solution matrix with carbides rich in chromium The specifications for selected cobalt alloys are given in Table 5

Cobalt Chromium Molybdenum

(Cast Vitallium Stellite 21, Vinertia, Zimalloy)

The development of this alloy by Austenal Laboratories is a truly remarkable achievement [16] First developed for the dental surgeons it later became prominent as a surgical implant and now has many uses in high temperature work such as turbines and rocket engines In this later use the superior resistance to creep and stress rupture of a modified Co Cr Mo (with 2 per cent nickel) were used during World War II

This alloy contains typically 61 and 62 per cent cobalt, 28 to 29 per

TABLE 5

Cobalt Alloys Typical Analyses

	C	Ni	Cr	Mo	Co	Fe	W
	per cent	*per cent*	*per cent*	*per cent*	*per cent*	*per cent*	*per cent*
Co Cr Mo	0.35	1.52	28.34	4.73	61.9	0.61	—
Co Cr Ni W	0.05	9.8	20	—	48	2.5	15.2
Co Cr Ni Mo Fe	0.15	15	20	7	40	7	—

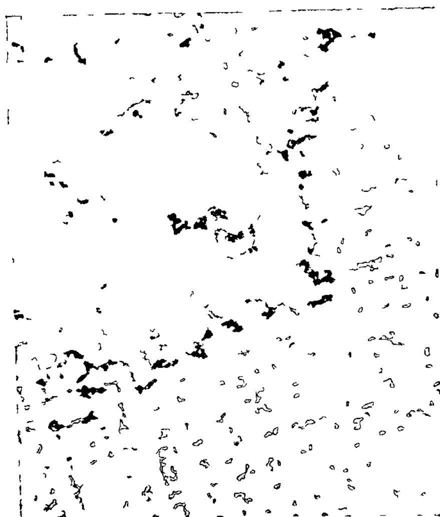


Fig 47 This metallurgical microphotograph shows the typical appearance of cast Co Cr Mo alloy Some spherical carbides are seen If these become a continuous line they may prove a site of weakness

cent chromium, 4.5 to 5 per cent molybdenum, 1.5 to 2 per cent nickel and less than 0.61 per cent iron The carbon content is around 0.3 to 0.35 per cent

Badger and Kroft[15] give the structure of Stellite 21 as partly hexagonal (alpha cobalt) and partly face centered cubic (beta cobalt) as cast, but as entirely face centered cubic as annealed A typical photomicrograph of the cast structure is shown in Figure 47

The main difficulty with this alloy that had to be overcome during the early stages of its development were faults in the cast products producing failure The cobalt base alloys in general are hard to machine, for they are more subject to work hardening than the A I S I 316 to 317 range The faults were the direct result of the fact that this alloy has to be cast The casting process used is the lost wax process which has been in use since the

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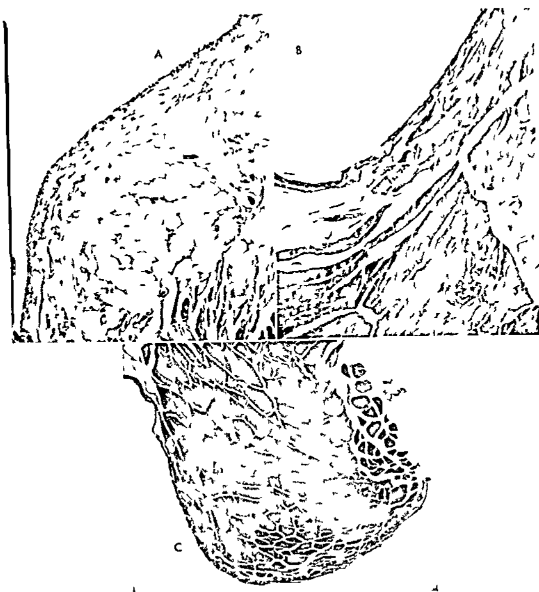


FIG 49 (A B and C) These three microphotographs show tissue that had been in contact with a Co Cr Mo implant for several months Decreasing tissue reaction is shown from A to C Normal tissues are seen in all only separated from the metal by a one or a few cells thick layer of parallel fibroblasts (× 360)

num is probably helped by the formation of chromates at the crystal boundaries and on the metal surface With cobalt alloys in general there is some analogy with the noble metals in that there is little tendency to displace hydrogen from solution under a variety of conditions There is some tendency to be sensitive to depolarization at the cathode Thus a high local oxygen concentration may be a danger The possibilities of galvanic corrosion exist and although the alloy will be the more noble member of the couple it is probably wise to avoid inserting Co Cr-Mo and A I S I 316 implants together until more is known about this aspect



FIG 48 This enlarged photograph of part of a Co Cr Mo bone plate shows a small crack at the apex of a bend produced by the surgeon to obtain good metal to bone contact This crack might be an example of stress corrosion cracking or the metal may have been strained beyond its yield point

days of Pharaohs This lost wax process has been developed to a point at which, through attention to details and by careful inspection of end products, a thoroughly reliable implant is produced The use of every modern testing means to detect casting faults is imperative The hardness of this alloy is usually around 28 to 30 on the Rockwell C scale It has superior strength properties, although not always superior to the stainless steels The tensile strength of Stellite 21 after annealing at 1500°F is about 59 000 p s i

CORROSION RESISTANCE

This alloy has truly remarkable resistance to corrosion cracking This process can however occur as is shown in Figure 48 It maintains its corrosion resistance in a chloride environment rather better than A I S I 317 [17] This good quality is to some extent given by the molybdenum contained

Its performance in the tissues has also been very good Tissue reaction around these implants is usually less than around stainless steel in so far as it can be judged cytologically (Fig 49) However, it must be remembered that these super alloys are all susceptible to the same corrosion processes as stainless steel [18] As has been pointed out spectrochemical analysis of tissues surrounding any metal implant will show them to be contaminated with the constituent elements of the metal This is true for cobalt chromium molybdenum In particular it may be true that a high oxygen environment may be dangerous for some of these alloys which is the converse of the truth for A I S I 316

The good corrosion resistance in general of cobalt chromium molybde

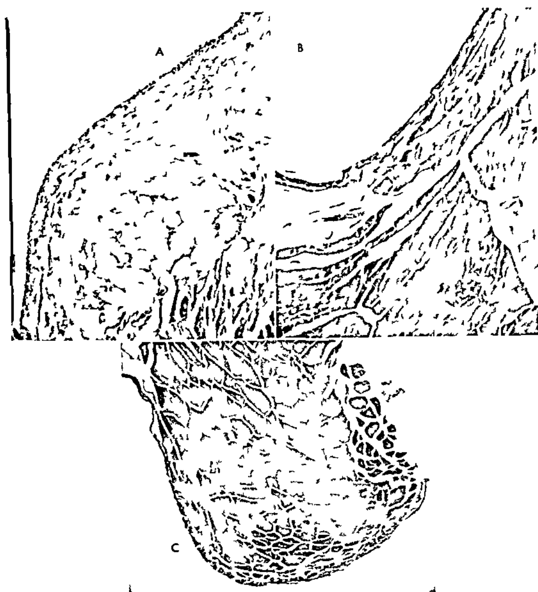


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Recently wrought vitallium has been put on the market It is discussed in the next section

Talking about cobalt alloys, in general one can quote from Weisert[18] who says "The alloys must be applied with good engineering discretion, keeping in mind that they are subject to the same basic principles of corrosion as are the more common materials of construction " He goes on to point out the dangers of crevice corrosion and the importance of correct designing to avoid it

One may list the advantages of this alloy as (1) superior corrosion resistance, especially in chlorides, (2) adequate strength for our purposes, and (3) tight specifications because of small melts being made at a time

The disadvantages include (1) a high local concentration of cobalt, chrome, and nickel in the surrounding tissues (this may prove to be of little importance), (2) the high cost of the alloy, and (3) difficulties of machining and the necessity for casting the implant

Cobalt Chromium Nickel Tungsten

(Stellite 25, Haynes 25, Neutrilium, and Wrought Vitallium)

This alloy was developed as a high strength sheet material for use at high temperatures (1800°F) It was found to possess superior corrosion resistant properties at all temperatures It is a cobalt alloy containing 46 to 53 per cent cobalt, 9 to 11 per cent nickel, 19 to 21 per cent chromium, 14 to 16 per cent tungsten less than 3 per cent iron and 1 to 2 per cent manganese

It has a face centered cubic structured matrix rich in cobalt and nickel plus some insoluble constituents There are some primary carbides of the M6C type present in the annealed condition [18] It may be both wrought or cast (Fig 50)

STRENGTH

This alloy is extremely strong and in the usual wrought form has an ultimate tensile strength of 140 000 p s i

HARDNESS

It is very subject to work hardening and in the form used for manufacture of implants under the trade name Neutrilium, it has a hardness value of Rockwell C 53 to 57 Its very susceptibility to work hardening makes machining difficult and various techniques such as upsetting apparently have to be used to make screw heads The forming behavior is similar to the austenitic stainless steels but needs more power for it is stronger



FIG 50 (A) A metallurgical microphotograph of worked Co Cr Ni W alloy The grain boundaries are clearly etched (B) This microphotograph shows cast Co Cr Ni W alloy and is very similar to the appearance of Co Cr Mo seen in Figure 47 (Microphotographs by courtesy of Haynes Stellite Division of Union Carbide)

Recently wrought vitallium has been put on the market. It is discussed in the next section.

Talking about cobalt alloys, in general one can quote from Weisert[14] who says "The alloys must be applied with good engineering discretion, keeping in mind that they are subject to the same basic principles of corrosion as are the more common materials of construction." He goes on to point out the dangers of *crevice corrosion and the importance of correct* designing to avoid it.

One may list the advantages of this alloy as (1) superior corrosion resistance, especially in chlorides, (2) adequate strength for our purposes, and (3) tight specifications because of small melts being made at a time.

The disadvantages include: (1) a high local concentration of cobalt, chrome, and nickel in the surrounding tissues (this may prove to be of little importance). (2) the high cost of the alloy, and (3) difficulties of machining and the necessity for casting the implant.

Cobalt Chromium Nickel Tungsten

(Stellite 25, Haynes 25, Neutrilium, and Wrought Vitallium)

This alloy was developed as a high strength sheet material for use at high temperatures (1800°F). It was found to possess superior corrosion resistant properties at all temperatures. It is a cobalt alloy containing 46 to 53 per cent cobalt, 9 to 11 per cent nickel, 19 to 21 per cent chromium, 14 to 16 per cent tungsten, less than 3 per cent iron and 1 to 2 per cent manganese.

It has a face centered cubic structured matrix rich in cobalt and nickel plus some insoluble constituents. There are some primary carbides of the M6C type present in the annealed condition.[18] It may be both wrought or cast *(Fig. 50)*.

STRENGTH

This alloy is extremely strong and in the usual wrought form has an ultimate tensile strength of 140 000 p.s.i.

HARDNESS

It is very subject to work hardening, and in the form used for manufacture of implants under the trade name Neutrilium, it has a hardness value of Rockwell C 53 to 57. Its very susceptibility to work hardening makes machining difficult and various techniques such as upsetting apparently have to be used to make screw heads. The forming behavior is similar to the austenitic stainless steels but needs more power for it is stronger.

TABLE 6
Commercially Pure Elements Typical Analyses

	C	O_2	N	Fe	Ti	H	Zr
	per cent	*per cent*	*per cent*	*per cent*	*per cent*	*per cent*	*per cent*
Titanium	0 03	0 06	0 04	0 25	Bal	—	—
Zirconium	0 15	0 07	0 1	0 75	—	1 9	Bal

CONSTITUTION

Commercially pure titanium has approximately 0 25 per cent iron, 0 03 per cent carbon and 0 04 per cent nitrogen (Table 6)

On solidifying from the molten state, it has a body centered cubic structure known as beta titanium At 1625°F as it cools it undergoes allotropic transformation to a hexagonal close packed form called alpha titanium A typical photomicrograph is shown in Figure 51 The prefix "A" is used to denote the pure alpha structure The number following denotes the tensile strength in thousands p s i Titanium alloys are thus "B" or beta, or "C" with a combined alpha and beta structure (Fig 52)

The ultimate tensile strength of the titanium used for the manufacture of implants is about 70,000 to 90,000 p s i In general terms, pure titanium is somewhat less strong than 316 stainless steel This is especially true of implants such as screws which can be badly damaged by a screwdriver during insertion They can also be more easily deformed by twisting while attempting to insert them than screws made from A I S I 316 or Co Cr Mo

Tensile strength appears adequate for use as implants when great strength is not required, but where excellent corrosion resistance is, *i e*, in hip molds and in arterial and cardiac surgery

MACHINABILITY

Titanium is easily weldable and machinable It can be cold worked with increase in strength and hardness It can be provided with a hardness of Rockwell C 28 to 30

The hexagonal close packed structure in metals is thought to give poor ductility and workability This is not the case for titanium or zirconium, both of which can be worked with ease at room temperature However, some clogging of the cutting edges of machine tools has to be watched for

CORROSION RESISTANCE

This element has excellent corrosion resistance, being as resistant as tantalum to acids superior to tantalum in alkalis and as good as platinum

CORROSION RESISTANCE

The cobalt chromium nickel tungsten alloy has unusual resistance to the halogens and is used in the manufacture of chlorine Tissue reaction to this alloy is comparable to that to cobalt chromium molybdenum Spectrographic analysis, however, shows that cobalt, chromium, and nickel are found in the tissues around such an implant Little tungsten can be demonstrated

This alloy is also subject to crevice corrosion and implants must be designed with this in mind In industry, severe pitting has been seen under retaining washers in a chloride environment

In conclusion this alloy has many of the advantages and disadvantages of the cobalt chromium molybdenum alloy, but is significantly easier to machine It may also be cast

Commercially Pure Elements

The main advantage of a pure element for the manufacture of an implant should be its corrosion resistance Platinum, gold, and silver, the noble metals, spring to mind However, our metal must also be strong enough to resist bending forces and fatigue In the past, much work has been done on the place of tantalum in surgery [19] In spite of the very good corrosion resistant properties, especially to acids, it has poor resistance to alkalis, but good resistance to the halogens up to 300°F Severe corrosion and fragmentation of implants has occurred in the body, however, and removed tantalum from our candidates for the ideal metal

At the present stage of our knowledge, there are two members of this group to consider These are titanium and zirconium which are closely related elements in the periodic table with very similar properties

Titanium

This element is very plentiful and forms 0 6 to 0 7 per cent of the earth's crust It is used as an alloying element in many steels Recently, it has been alloyed itself with other elements giving the titanium based alloys These are now under investigation with regard to their use in the manufacture of implants

Commercially Pure Titanium

Commercially pure titanium comes in several grades and each manufacturer has his code for these For instance, a common one is a grade called A70 with strength properties more suitable for the manufacture of implants than the others

A B C OF TITANIUM ALLOYS

A: ALPHA (α)

B: BETA (β)

C: COMBINATION OF ALPHA & BETA

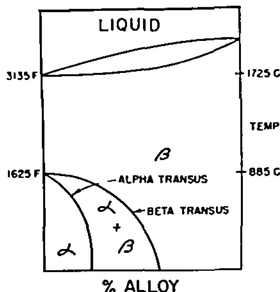


FIG 52 Constitutional diagram for titanium and its alloys Titanium solidifies as beta titanium with a body centered cubic structure and changes to the alpha structure (close packed hexagonal) on further cooling Vanadium chromium and aluminum stabilize the beta structure whereas manganese and aluminum together stabilize the combined structure which is somewhat similar to martensite in steel giving great strength (Courtesy of Titanium Division of Crucible Steel Corp)

in sea water and chlorides in general [0] The excellence of its performance in sea water is mentioned by Raudebaugh [1] Titanium and its alloys are particularly resistant to crevice corrosion and to stress corrosion cracking If the strong alloys retain the corrosion resistance of pure titanium they may prove of great interest to the manufacturers of implants

As with other metals relatively large amounts of titanium can be demonstrated in tissues around implants The significance of this is as yet unknown Normal rabbit muscle contains a fair amount of titanium as an apparently normal trace element and the amounts found round the implants may prove to be harmless

In summary, pure titanium is very inert perhaps the most inert usable metal but is not as strong as A I S I 316 or 317 stainless steel or the cobalt alloys [3, 4, 5, 6] It has a place for use as an implant where corrosion resistance is the main consideration and strength a minor one Titanium alloys may prove to be both sufficiently strong and corrosion resistant for surgical use

Zirconium

Zirconium is very closely related to titanium and has most of the advantages and disadvantages of the latter It is a very common metal forming 0 04 per cent of the earth's crust more than the combined values for copper lead zinc, tin nickel, and mercury [7] The chief impurity in this

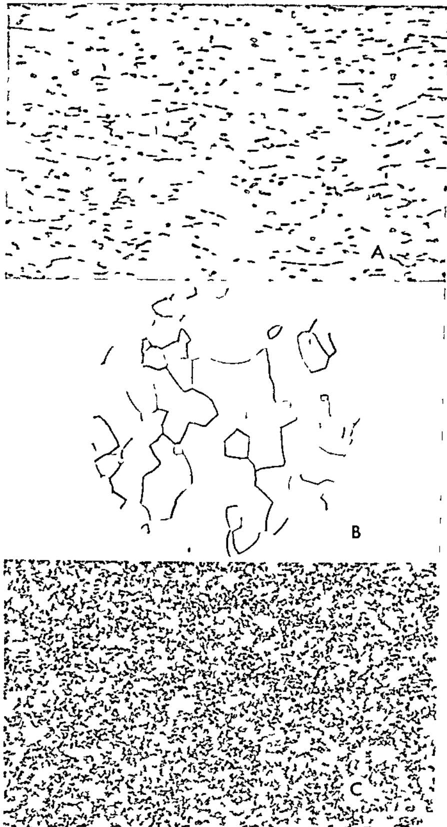


Fig 51 (A) Microphotograph of commercially pure titanium of A70 grade with alpha or close packed hexagonal structure and a ultimate tensile strength of 70 000 p s i (B) Micro photograph of a titanium alloy B120 with a beta or body centered cubic structure a strength of 120 000 p s i (C) Microphotograph of a titanium alloy C130 with a combined alpha and beta structure and a strength of 130 000 p s i (Photographs by courtesy of Titanium Division of Crucible Steel Corp)

A B C OF TITANIUM ALLOYS

A: ALPHA (α)

B: BETA (β)

C: COMBINATION OF ALPHA & BETA

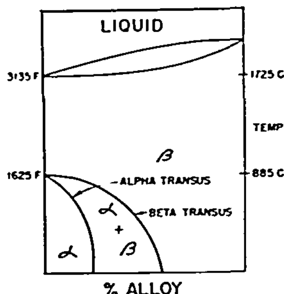


Fig. 52 Constitutional diagram for titanium and its alloys Titanium solidifies as beta titanium with a body-centered-cubic structure and changes to the alpha structure (close packed hexagonal) on further cooling Vanadium chromium and aluminum stabilize the beta structure whereas manganese and aluminum together stabilize the combined structure which is somewhat similar to martensite in steel giving great strength (Courtesy of Titanium Division of Crucible Steel Corp)

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metal is hafnium in 1 5 to 2 per cent When this element has been removed zirconium finds employment in atomic reactors

COMMERCIALLY PURE ZIRCONIUM

This grade has been used for the manufacture of implants both in the United States and Great Britian [28] Up to now the expense of this metal, like that of titanium, has been a deterrent to its wide adoption for this purpose The increased use of zirconium and its alloys will probably help in this respect

COMPOSITION

A typical analysis shows hafnium 1 9 per cent, carbon 0 15 per cent, nitrogen 0 10 per cent, oxygen 0 07 per cent, iron 0 75 per cent, chromium 0 04 per cent, nickel 0 01 per cent, and silicon 0 015 per cent (Table 3)

CRYSTAL STRUCTURE

This is similar to that of titanium, being hexagonal close packed (alpha zirconium) at room temperature and undergoing allotropic transformation to beta zirconium which is body centered cubic, at 1585°F

STRENGTH

The strength of commercially pure zirconium is similar to that of titanium It can be produced in bar form with an ultimate tensile strength of over 90,000 p s i

WORKABILITY

In spite of its hexagonal structure zirconium can be freely worked at room temperatures It can be machined almost as easily as stainless steel, but very fine turnings may ignite in air This reminds us that zirconium powder has been used as a photographic flash powder

HARDNESS

The hardness of zirconium is greatly dependent on the oxygen and nitrogen content [9] and these are kept as low as possible at all stages of manufacture It can be cold worked with resultant increase in strength and hardness It can be prepared with a Brinell hardness of 175 to 275 (Rockwell C 10 to 30), and for implants it should be at the top of this range

CORROSION RESISTANCE

The corrosion resistance of zirconium is very high and is very similar to that of titanium It is not attacked by atmosphere or sea water and is more resistant that tantalum to alkalis and nearly as resistant to acids

USE FOR IMPLANTS

Zirconium has similar advantages and disadvantages to titanium and it is difficult to give one precedence over the other Both seem to have a great future and some of their alloys may prove very interesting to surgeons

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4

METALLIC TRANSFER

Patrick G Laing, M.D

When a pencil point moves over a piece of paper it leaves a mark This mark is produced by a transfer of graphite from the pencil to the paper, a fact which is well known to everyone It is not so well known, however, that a similar phenomenon is produced whenever one metal surface touches another one

This so called metallic transfer is probably of great importance in the control of corrosion in all fields of life where metal is used It is very important that surgeons should understand this process and the dangers entailed in the handling of metal implants Much time and energy has and is going into the selection of inert metals for use as implants Surely it is worth a little effort to ensure that these implants are not contaminated by noncorrosion resistant fragments during insertion?

The Nature of Metallic Transfer

It has been shown by Bowden and Tabor[1] that, whenever one piece of metal comes into contact with another, transfer of small particles of one to the other probably occurs (Fig 53) In order to understand this process, it is necessary to realize that under the electron microscope the most highly polished surface of metal is really a very rough terrain indeed Mountains and valleys crisscross the surface When two such surfaces are brought into contact it is immediately seen that the whole of the areas apparently available cannot touch It has been shown by experiments involving the calculation of the electrical resistance of two blocks in apparent full contact that something like one ten thousandth part of the total area is often all that is actually touching Why is this so? It is rather as though one had inverted the Rocky Mountains and laid them on the Andes Only the high peaks will touch All the weight of the metal is thus taken on a very small area and at the points of contact very high pressures indeed develop, probably going into many hundreds of pounds per square inch The mountain peaks on the metal surface flatten and

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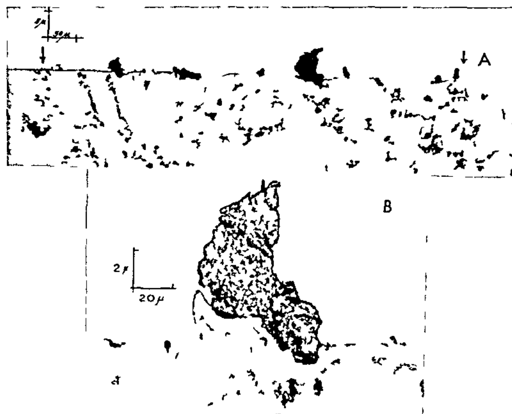


Fig 53 (A) Microphotograph of a taper section of a steel surface after a piece of copper had slid over it Fragments of copper (dark) are seen adhering to the steel Note the rupture of the steel surface This transfer is typical of any metal to metal contact (Courtesy Dr A J W Moore) (Magnification horizontal × 2 000 vertical × 20 000) (B) This greatly enlarged portion of (A) shows some detail of metallic transfer of the grossest type The transferred particle of copper is large probably because copper is so much softer than steel Even so the steel has been plucked up by the force necessary to fracture off the copper fragments (Dr A J W Moore courtesy of Journal of Bone and Joint Surgery)

deform until enough metal has come into contact to support the pressures applied At this stage the two metal surfaces are found to be "cold welded together at the points of pressure When the two metals are separated usually by sliding then instead of the welds breaking, fracture occurs through the base of one or other of the metal peaks This is aided by the work hardening undergone by the metal adjacent to the weld caused by the deforming force of the contact pressures Fracture has occurred on one or other side of this zone This process is shown diagrammatically in Figure 54

Relation of Metallic Transfer to Corrosion

The experiments undertaken to investigate this process were triggered by the accidental discovery that corrosion always seemed more marked

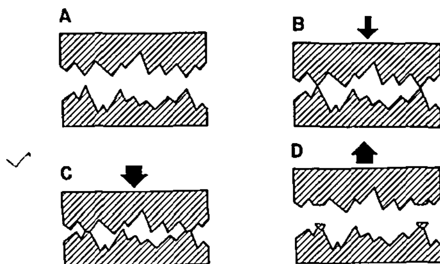


FIG 54 Diagrammatic representation of metal transfer (A) Two metal surfaces approach each other Roughness is exaggerated and must be considered as visible under an electron microscope (B) Contact has occurred between the mountain peaks in two places (C) Force is applied and the projections flatten until their area of contact can resist the force (D) The two metal surfaces are separated Two small pieces of the upper one remain cold welded to the lower surface Metallic transfer has occurred

around the parts of metal implants that had been handled than around unhandled surfaces [7]

The probable reason for this corrosion is that metal transfer seeds the surface of the supposedly corrosion resistant implant with pieces of an alloy having a different composition Mixed metals are being inserted since the tool alloy is usually some noncorrosion resistant tool steel In any case, even if the two alloys are very similar in specification, their metallurgical condition will usually differ profoundly This is especially true after the transferred pieces have been plastically deformed during their exposure to large pressures All the dangers of inserting mixed metals are inherent in any situation where metallic transfer can occur [8]

Corrosion currents can start at these sites of welded metal couples and lead to severe cathodic attack on the implant This appears to be the case even if as is usual, the implant is the nobler of the two alloys in contact Another source of danger to the implant is the damage to the protective oxide film on its surface which is probably unavoidable in metal to metal contact There is reason to believe that the ability of metals to heal such defects in the oxide film is at the base of much corrosion resistance If the defect is larger than a certain "critical" size the metal may not be able to heal it and so the bare metal will be exposed to pitting corrosion

Experimental Investigation

Animal experiments have seemed to confirm this clinical observation [7] Experiments were undertaken that had some very interesting results If one makes the tip of a screwdriver radioactive and then drives a screw into a predrilled hold in soft wood any transfer from the driver to the screw should be easily demonstrated by the acquired radioactivity of the screw slot This is in fact what happens as is shown in the radioautograph (Figs 55 and 56) taken from some screw heads after just such an ex

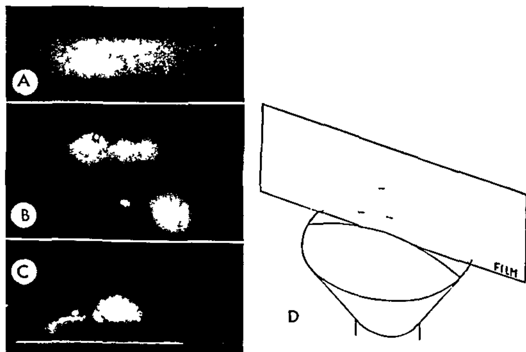


FIG 55 Radioautographs of screw slot handled with radioactive screwdrivers acquire radioactivity by metallic transfer (A) Handled lightly with little slip 22 mg of transferred metal (B) Slightly greater slip 47 mg of transfer (C) Distribution of transferred metal within the screw slot (D) Position of film to obtain view shown in C (Courtesy of Nature London)

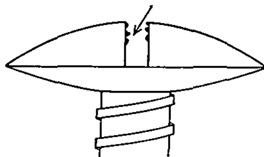


FIG 56 Diagram of screw head showing where adherent metal was detected (Courtesy of Nature London)

periment The actual amount of transferred metal can easily be calculated by counting the radiation from the screw head using a scintillation tube, knowing the radiation per milligram of the tool metal Tissue reaction to metal appears to be proportional to the amount of metallic transfer, other things being equal (Figs 57, 58, and 61)

It has been shown that metallic transfer is in general greatest between like alloys and less between alloys of differing compositions This is only strictly true where there is no great difference in the hardness of the metals, for both the metallurgical condition and composition are important factors Metal transfer is greatest from a soft metal to a hard one and least from a hard metal to a soft one Such transfer is probably materially reduced by lubricating surfaces adequately and is definitely increased by increasing the pressure of tool on implant and by any slipping that inadvertently occurs This fact reinforces our belief that screw-holding screwdrivers properly handled are a great factor in cutting down corrosion at the screw head

Similar radioisotopic techniques have been used to investigate metal transfer during the tightening of a nut on a bolt, when the transfer is on occasion very large and may lead to severe surface pitting of the nut (Fig 59) and a marked tissue reaction (Fig 60)

One of the most important examples of metal transfer is that which takes place during the hammering home of a nail, for example a Smith-Petersen nail (Fig 61) The punch often used in these cases is made of some noncorrosion resistant metal and large amounts of transfer from it to the nail can be expected The metals will differ both in composition and hardness The direct use of a metal headed hammer on an implant is not to be recommended for a similar reason In most cases some form of screw home introducer is available which eliminates direct contact between punch or hammer and nail

Whenever an osteotome is used to cut bone the bone is seeded with the metal of the osteotome Perhaps this can be reduced by using tungsten carbide tipped osteotomes which have the added advantage of a superior cutting edge

Rotating or oscillating saw blades have also been investigated and transfer occurs both to the cut surfaces of the bone and to the bone dust

During the drilling of a hole into bone to receive a screw there are two dangers First there is the obvious one of transfer of drill metal to the bone hole down which an inert screw is to be placed Second, unless some form of guard is used to protect the bone plate when drilling through the holes in it then it is all too easy to allow the rotating drill to touch the plate It has been shown that several milligrams of metal may be transferred at such an accidental contact [10] In general, it has been clearly

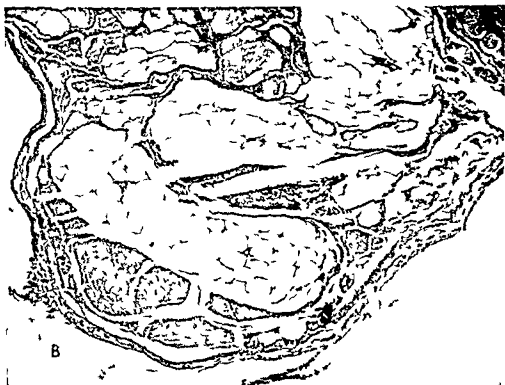


Fig 57 (A B C D E and F) The e six microphotographs show tissue from the inside of screw lot after three month contact The amount of slip increa ed from A to F and so does the t ue reaction to the m tal (Courte y of Journal of Bone and Joint Surgery)

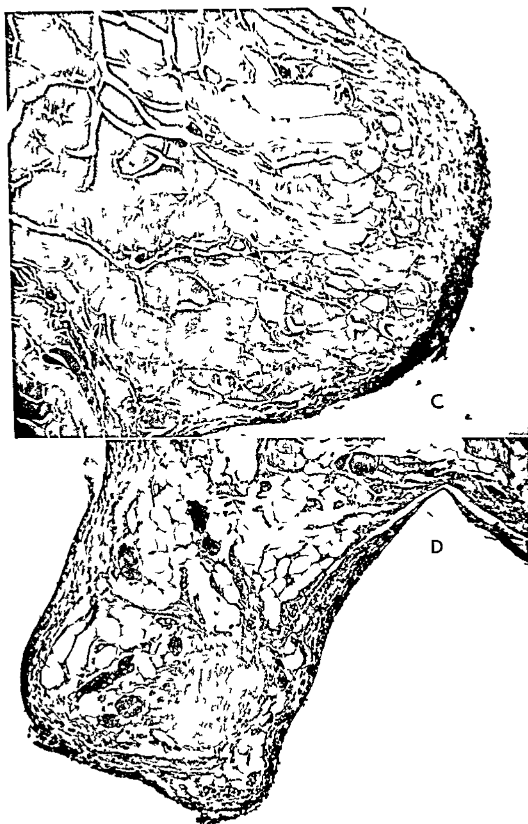


FIG. 57. C and D. See legend preceding figure.

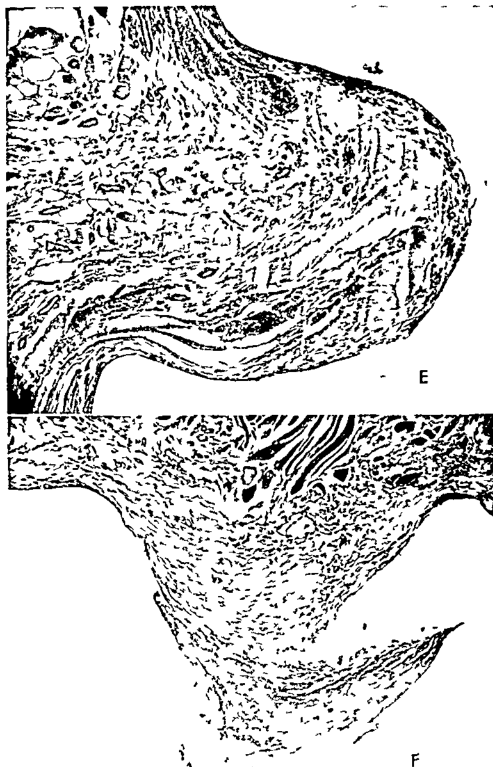
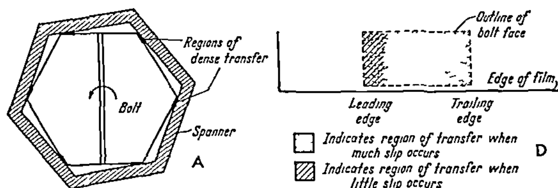


Fig 57 E and F See legend preceding figure



Fig 58 A strip of tissue removed from a screw slot and stained for iron by the Prussian blue method The black particles are iron salt This screw had been handled with a tool steel screwdriver (Courtesy of Journal of Bone and Joint Surgery)



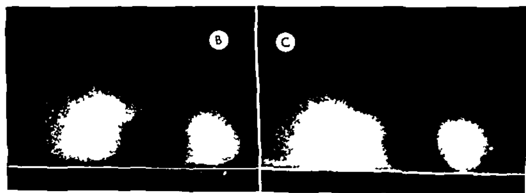


Fig 59 Autographs of transferred metal on bolts (A) Manner in which spanner grips a bolt (B) Distribution of transfer from radioactive spanner with minimal slip (C) Heavier transfer with slip of spanner on bolt (D) Diagrammatic explanation of B and C (Courtesy of Butterworth s Scientific Publications)



Fig 60 (A and B) Tissue reaction around stainless steel bolts that had been firmly tightened with a spanner The black areas consist of iron salts made visible by the Prussian blue reaction (× 70)

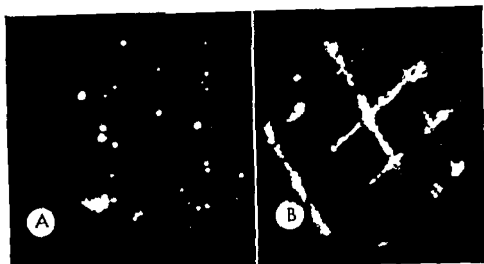


Fig 61 (A) Autoradiograph showing metal transferred from a hammer during a single blow on a flat copper surface (B) Autoradiograph showing metal transferred during a single hammer blow on a nail head (Courtesy of Editor of Engineering, London)

demonstrated that the more often a drill has been used, the less transfer will occur from it to bone However, such well used drills are often dull so that is small consolation Significant metallic transfer has been shown to occur when metal is machined[11] (Fig 62) The use of electrolytic polishing may remove some of this but it may be a very real danger in the corrosion of implants

Surface Damage in Relation to Metal Transfer

Most scratches and dents on the surface of a metal implant are produced by another piece of metal This scratch may have been produced during manufacture, or during storage in the operating room drawer, or during handling with hemostats or screw holding forceps during the operation itself Any such scratch is probably seeded with pieces of the metal edge that produced it Not only is the protective surface oxide film damaged, but fragments of a foreign metal are welded onto it and in addition the metal on each side of the scratch is plastically deformed Each one of these three factors is a direct threat to the passivity or corrosion resistance of the implant It all makes a very sorry tale and especially in the case of so called stainless steel where the surface conditions are critical to continued corrosion resistance

Macroscopic Metal Contamination

During radioisotopic experiments undertaken to discover the most suitable metal out of which to make screwdrivers an interesting observation was made [12] During this experiment orthopedic screws made of four different metals were being screwed home into predrilled $\frac{7}{64}$th inch holes



FIG 60 (A and B) Tissue reaction around stainless steel bolts that had been firmly tightened with a spanner The black areas consist of iron salts made visible by the Prussian blue reaction (× 70)

radioautographs. The large metal flakes that had presumably been cut off the screwdriver by the edge of the screw slot can be clearly seen in Figure 63.

Observations have been made by many surgeons that hammers are

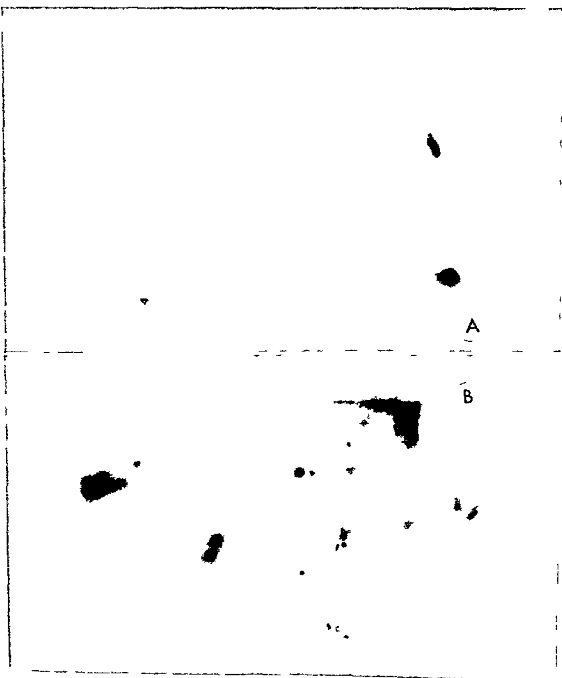


Fig. 63. (A) Autoradiograph of twelve screws handled with a radioactive screw driver. No attempt to trap any loose particles of the tool. (B) A similar autoradiograph but here a layer of plastic has trapped loose tool fragments which would otherwise have fallen off. Note the heavy radioactivity scattered around the screws as well as that in the screw slot.



FIG 62 Autoradiograph of the end of a copper rod machined by a radioactive tool It will be seen that the metal from the tool is distributed in a few discrete arcs The work was lubricated during machining (Courtesy of Editor of Engineering London)

in soft white pine The radiation transferred from the drivers to the screw heads was then counted by mounting the blocks on their sides in front of a scintillation counter It was noted during the counting that the bench underneath the blocks was becoming contaminated by quite large fragments (1 to 2 mm) of radioactive metal from the screwdrivers and that the background count was rising That this was happening was confirmed by running a coating of plastic over the screw head and adjacent wood after handling with the radioactive drivers and before making

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particularly prone to shed surface fragments in use with obvious dangers to the implant. Plastic faced hammers are available which exchange this danger for the unknown one of leaving flakes of plastic in the wound. This last point may prove to be of little importance.

The possible dangers to the healing of fractures and the life of implants are evident. Nobody would willingly seed a hip arthroplasty wound with fragments of tool steel just before inserting a mold or prosthesis that is expected to remain free of corrosion for several decades of the patient's life.

Relation of Tool to Implant Alloy

Previous animal work has been done to attempt to find a suitable alloy for making screwdrivers and other tools.[2]

In the experiments just described orthopedic screws made of four metal were tested against screwdrivers of several suitable alloys using radioisotopic techniques.[3]

The screws were made of the four metals in anything like common use, *i.e.*, stainless steel type A.I.S.I. 316, cobalt chromium molybdenum (vitallium), cobalt chromium nickel tungsten (neutrilium), and commercially pure titanium (Grade A70 of Mallory Sheron Corp.). The drivers were made of tool steel A.I.S.I. 316, A.I.S.I. 410 stainless steel, A.I.S.I. 420 stainless steel and also of Co Cr Mo alloy.

The details of the results obtained will be presented elsewhere. Taken in conjunction with the behavior of handled screws in rabbit muscle it is of interest that for the A.I.S.I. 316 and titanium screws the A.I.S.I. 420 screwdriver gave the least transfer, and for the Co Cr Mo and Co Cr Ni W screws the Co Cr Mo driver was the best.

In summary it can be said that metallic transfer and tool flaking are facts which the surgeon should probably take into account if he wants the metal he implants in the body to give the best service. The practical answers suggested will be given in detail in the next chapter.

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Fig 64 (A and B) Antero posterior and lateral radiographs of vanadium steel plate and screws inserted some 20 years previously to treat a fractured femoral shaft The fracture united and all went well until the leg suddenly became tender and swollen Gross corrosion of the implant is visible with almost complete disintegration of the screws The plate is practically corroded through at its center A marked periostitis is seen in the complete absence of infection

liable to corrode in the body (Figs 65 and 66) Within the range of A I S I 317 or 316 if this is the final choice the chemical composition should probably be in the upper range of chromium, nickel, and molybdenum It might be wise to specify a narrow range, *e g*, chromium 19 to 20 per cent, nickel 12 to 14 per cent, and molybdenum 3 to 3 5 per cent, and ask the steel mill to send only those melts of A I S I 317 which fall in this range For manufacturability three quarters hard is a satisfactory hardness and corresponds for this grade of stainless steel to about 30 to 35 Rockwell C Cater and Hicks[3] and Capener[4] have discussed the types of stainless steel available in Great Britain

It is to be recommended that all parts of those appliances having

5

THE USE AND CARE OF METALS

Patrick G. Laing, M.D.

We have now considered the basic applied metallurgy of the surgical implants we use daily in orthopedic surgery. An attempt has been made to provide some of the information necessary for a more complete understanding of the advantages and disadvantages of metals as implants. By applying some of these observations to our practice we may hope to reduce the chances of the implant's letting the patient down by failing either dramatically by fracture or less obviously by corroding (Fig. 64).[1] The life of an implant starts with the preparation of the parent alloy, goes on to include its manufacture in the factory, and then continues in the operating room where it is cared for by nurses and physicians. The implant is then inserted into a patient where it may stay a short or a long time, even for a lifetime. Each aspect of this story will now be considered in turn and an attempt will be made to interpret some of the information provided in earlier chapters into practical advice or suggestions.[2]

Manufacture and Packaging

Condition of the Parent Metal

Some manufacturers of metal implants make their own alloys. By making small melts and by paying great attention to the details of the process, melts prepared at different times will have a very similar composition. Other firms who may use A.I.S.I. 316 and 317 stainless steel, Haynes 25, or titanium are to a great extent dependent on the supplying mill. However, it is usual practice to send a certified spectrographic analysis report with each batch of metal delivered. The manufacturer is thus aware of the composition of the alloy he uses from day to day and is in a position to accept or reject particular metals.

It is probably advisable that manufacturers using stainless steel should use A.I.S.I. 317 and not the slightly inferior A.I.S.I. 316 which is more

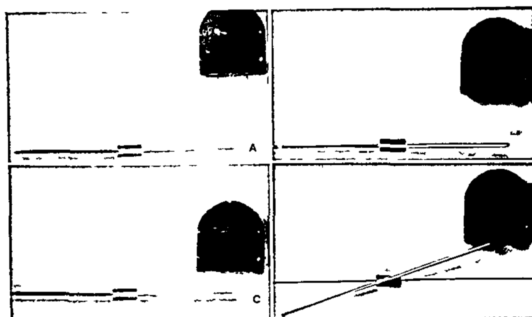


FIG 66 Austenitic stainless steel is not magnetic whereas the ferritic and martensitic forms are attracted by magnet (A) An austenitic nail (B) The nail shown in Figure 65 (C) A magnet has no effect on the A I S I 316 nail but (D) it attracts the martensitic nail strongly This test of magnetism quickly distinguishes the two steels in any operating room cupboard

has been mentioned as fairly simple to control The hardness varies little and averages about Rockwell C 28 to 30 The process is controlled so that spherical carbides do not form continuous lines and so provide weaknesses in the cast structure

Titanium implants are usually made from a commercially pure grade with an ultimate tensile strength of about 70,000 p s i and a hardness of about 26 to 28 Rockwell C The actual strength is often a great deal higher i e 90,000 p s i

Cobalt chromium nickel tungsten (neutrilium) and wrought vitallium implants should probably also be made from melts of very similar composition and having roughly similar metallurgical conditions

Manufacture of Implants

A I S I 317 stainless steel implants are apparently best forged for maximum resistance to fatigue They are also satisfactorily machined or wrought and in these instances their corrosion resistance may be better The ordinary rules for good machine shop practice apply here with extra emphasis It is obviously to the good if the dimensions of, for example, all screws are within a tight tolerance It is unfortunate if the threads have very different depths and thicknesses[16] This applies also to the thickness and depth of slots in the screw heads Examination of over 500 orthopedic screws as bought has revealed that large differences in these



FIG 65 This radiograph of a united fractured femoral shaft shows a 18 8 S Mo stainle steel intramedullary nail and A I S I 316 stainless steel screws The e mixed metals left in long after they had done their job started to corrode and cau ed swelling of the leg pain and tenderne The maximal bone atrophy and perio titi is een at the site of the mixed metal

several pieces *i e* a McLaughlin nail and plate should be in the same metallurgical condition (Fig 67) This includes hardness and grain size For optimum performance of A I S I 317 a grain size of 6 or 7 should be present 8 being the smallest size recognized A large grain size *i e* below 6 or 7 is very liable to lead to failure in use either from stress corrosion cracking or fatigue As far as implants manufactured from cobalt chromium molybdenum alloys are concerned the composition of each batch

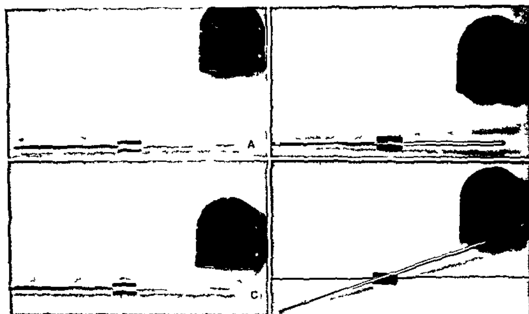


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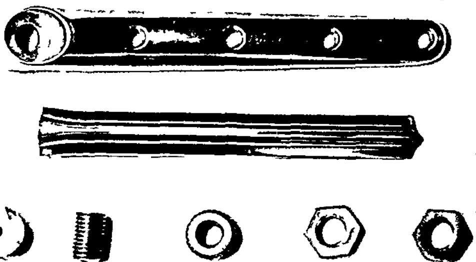


Fig 67 This photograph shows the separate parts of an intertrochanteric appliance Each part is in a different metallurgical condition The hardnesses on the Rockwell C scale are 41 8 for the plate 10 5 for the nut and 7 for the nail Apart from considerations of strength these different hardnesses mean that different metals have been inserted with severe risk of corrosion unless they are removed promptly after the fracture has united

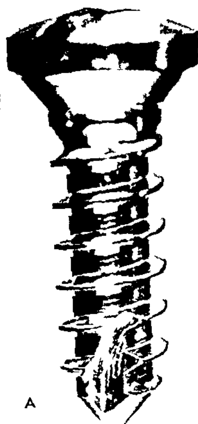
dimensions are sometimes present not only between different screws made by different firms but also between different screws made by the same firm (Fig 68) Standardization of sizes is also desirable Probably a so called 2 inch long screw should have 2 inches of effective thread to hold bone if measuring the pilot hole with a depth gauge is to mean anything This means of course, two inches from the undersurface of the screw head to the last thread The pilot point obviously has no holding power (Fig 69)

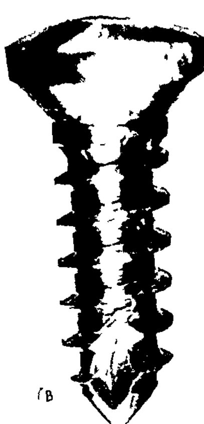
WELDING

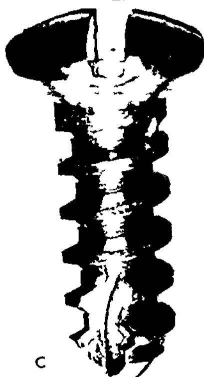
Welding of implants is on the whole an undesirable practice Apart from the difficulties of avoiding cracks and cavities in the weld itself, there is another disadvantage On either side of the welded junction is a heat affected zone where corrosion can get started and cause failure of the implant by fracture (Fig 70)

INSPECTION

Many firms have a truly excellent inspection system for their implants A special method is used to detect surface defects A highly detergent substance is used to find any surface defect when the implants are dipped into this fluid it finds surface defects and enters them The outside fluid is then washed off After powdering with a special preparation examina







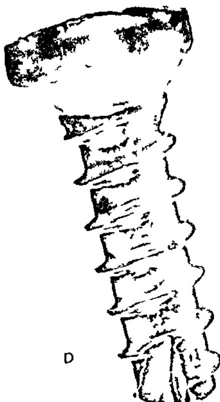


Fig. 68. (A, B, C, and D) These photographs of three cross slotted coarse threaded bone screws demonstrated the lack of standardized dimensions prevalent today. From A to C the threads became increasingly thick. D shows an example of very shallow threads with the bottom one almost paper thin. This lack of standardization extends to slot widths. The screwdriver may be too wide to remove a screw with a very *narrow slot*.

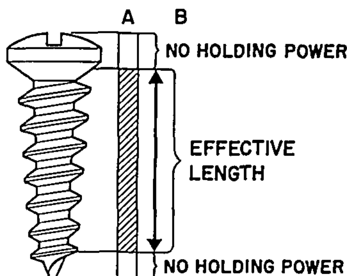


FIG 69 This diagram shows the difference between total length and the effective holding length of a screw When one measures the drilled hole in the bone and the depth gauge says $1\frac{1}{2}$ inches will a $1\frac{1}{2}$ inch screw reach the opposite cortex? Only if there is $1\frac{1}{2}$ effective *inches available to grip the bone The pilot point and last turn of the thread may be too* narrow to even touch the pre drilled hole

tion under ultraviolet light reveals where the detergent has penetrated the metal for it now seeps out again and fluoresces

X rays reveal hidden faults such as the one shown in Figure 71 X rays are especially useful in examining cast material for hidden imperfections

Visual inspection is used to find and then to remove all surface debris, burrs and any metal turnings left after machining Occasionally small burrs are missed (Fig 72) These pieces of plastically deformed metal may serve as centers for corrosion to start All cannulated nails and screws are carefully tested by some manufacturers so that the recommended guide wire size will drop through aided only by gravity There is thus no danger of having the nail bind on the wire during insertion It requires great skill to drill a hole through, for instance, a Smith Petersen nail It is usually done by drilling from either end and meeting in the middle A slight error leads to a step which may catch the guide wire during the nail's insertion and drive it into the pelvis (Fig 73)

POLISHING AND PASSIVATION

The final preparation of many implants necessitates very careful attention to their surfaces The removal of obvious metal burrs and turnings has been mentioned Electrolytic polishing or so called reverse plating removes surface debris and also some of the surface of the metal, making it very bright [7] It also probably removes metal transferred to the

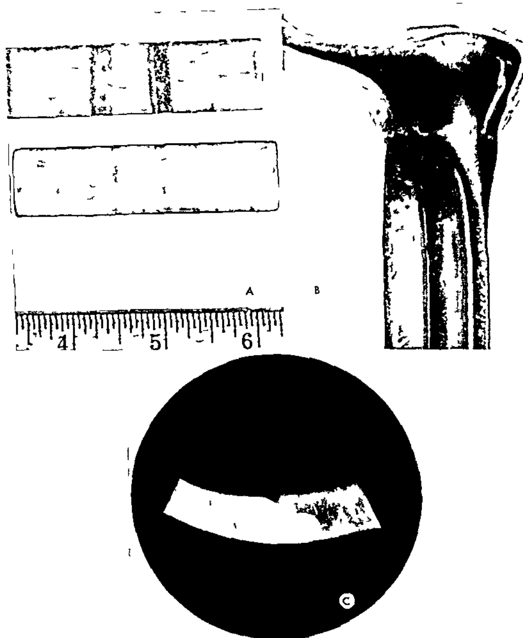


Fig. 70 (A) Corrosion on either side of a weld These two steel bars each consist of two bars welded together at the middle Artificial corrosion in a chemical shows how the attack occurs on either side of the weld at the heat affected zone (Courtesy of Crucible Research and Development Laboratory) (B) This photograph of a nail plate with a welded junction demonstrates corrosion on the nail adjacent to the weld The metal surface is severely pitted after only a few months in the body (C) Photograph of an etched metallurgical specimen showing a welded head of a femoral prosthesis In order to make the globular head two half globes may be fitted together then welded The site of welding is surrounded by altered metal structure resembling ripples spreading from a stone dropped into water

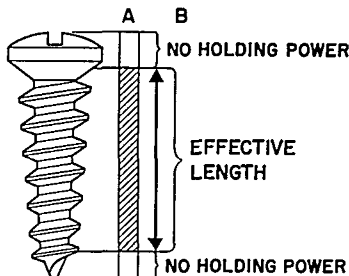


FIG. 69. This diagram shows the difference between total length and the effective holding length of a screw. When one measures the drilled hole in the bone and the depth gauge says 1½ inches will a 1½ inch screw reach the opposite cortex? Only if there is 1½ effective inches available to grip the bone. The pilot point and last turn of the thread may be too narrow to even touch the pre-drilled hole.

tion under ultraviolet light reveals where the detergent has penetrated the metal for it now seeps out again and fluoresces.

X-rays reveal hidden faults such as the one shown in Figure 71. X-rays are especially useful in examining cast material for hidden imperfections.

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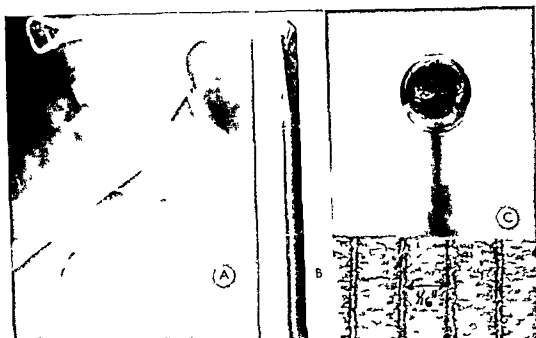


FIG 73 Antero posterior radiograph of a nail being inserted to hold a fractured neck of femur The guide wire has been pushed across the hip joint and has broken at the extreme end of the nail (B) Examination of the guide wire after removal shows that fracture occurred through the groove marking the third half inch This guide wire had probably been quietly corroding at this crevice for many months before breaking under stress (C) Photograph of the end of the broken guide wire showing corrosion of at least 9/10th of its cross sectional area The last bridge broke at the operation

implant during turning Sometimes hot nitric acid is used to passivate the implant, *i e*, to make it less liable to corrode This powerful oxidizing agent will probably produce a thick oxide sludge on the surface which may act as a better anticorrosion shield than would the oxide layer automatically formed by contact with air A highly polished surface is used with A I S I 316 and 317 and titanium products, but not for the cobalt alloys where a roughish satin like surface is considered desirable

STAMPING OF IMPLANTS

The question of whether or not one should stamp size and trade names on implants is a vexing one The inevitable effect of such stamping is the deformation of the underlying metal and also the production of crevices at the bottom of which crevice corrosion might start On occasion however, vanadium steel plates have still had a readable trade mark when removed in a grossly corroded form several decades later In this connection it has been pointed out that even the cobalt alloys are not free from the danger of such attack The avoidance of all sharp angles and notches is essential to good engineering design of parts which will be exposed to corrosion and stresses Although it cannot be pontifi

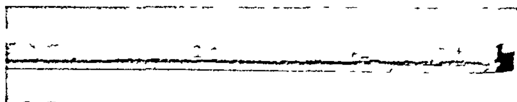


Fig 71 This bone plate showed no surface defect and routine testing by the manufacturers revealed nothing amiss Corrosion however found a linear crack along its side and opened this up Even the most excellent inspection system may overlook such a defect

Fig 72 These enlarged photographs of two screw ends show typical burrs left after machining (A) The tip of the self tapping flute ends in a wave of deformed metal (B) The place where the flute crosses the last thread shows a large turned down metal burr Only occasionally do these burrs escape the eye of the inspector They are however a very possible source of corrosion as the metal is grossly worked and deformed

PACKAGING OF THE FUTURE

Manufacturers of sutures and adhesive surgical drapes provide their products ready sterilized and inside at least two and sometimes three covers of various types. Is it too much to hope for that sometime in the near future manufacturers of implants will provide them ready sterilized inside at least a double envelop of plastic of some sort? Cutting the outside envelop open would allow the extraction of the sterile inner envelope and then by opening this last one with sterile scissors the scrub nurse could remove the sterile screw or plate and hand it to the surgeon. This implant would have been heated in the autoclave only once and would never have had the chance to become damaged accidentally in storage or repeated autoclaving.

Storage and Sterilization

The main thought underlying this section of this chapter is to avoid any damage to the implant from the moment it is received from the manufacturer until the surgeon inserts it into the patient. Naturally, a full range of each type of screw, nail, plate, mold, or prosthesis the surgeon uses must be available for each case. At the same time each implant, which may have to stay inside the patient's body for several decades, must be given the best chance of avoiding damage to its surfaces and metallic transfer from operating room storage drawers, other implants, storage racks and other metal parts. The last part of the previous section is pertinent to this subject. Ideally, the implant should remain so protected until the surgeon has chosen the actual size he wants at the operation.

At the present time, however, certain practical suggestions can be offered.

Cloth holders can be made quite easily which will hold a full range of screws (Fig. 75) or nails (Fig. 76). Any type of implant can be so packaged by the operating room staff and autoclaved in suitable extra wrapping. Each implant is thus individually protected from contact with other metal. It is probably inadvisable to use metal racks and stands to hold implants as the metal to metal contact is certainly deleterious both from the point of metallic transfer and of scratches on the surface of the implants, especially around the neck of the screws. It is also advisable to leave extra implants within the plastic bags they are supplied in until needed to replenish the complete range kept in the cloth bags.

There is a tendency to keep old implants, obsolete in style or in metal from which they were made, in the operating room drawer and to let them rattle around with the new implants which have been removed

cated about, one would still feel happier if manufacturers desisted from such practices whenever possible.

Packaging

At the moment metal implants are usually provided in sealed plastic envelopes labeled with size and type of appliance. Screws are usually packaged in batches of six. Plates and other implants are put up separately. It is probably desirable to protect all implants from contact with either other implants or with other metals, from the moment they have been finally "finished" in the factory to the moment they are inserted into the patient. In this manner, metal transfer from metal to metal contact will be reduced as will all surface scratches and marks. This could be achieved in the case of screws by packaging them separately or in separate compartments of a plastic bag so that each one could be removed separately (Fig 74).

Some manufacturers protect the sharpened ends of tri fin nails with a plastic coating. This is a very good idea. It brings up the thought that sharpness of the ends of tri fin nails is a highly desirable characteristic

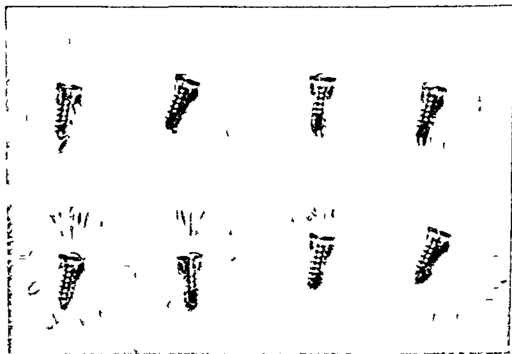


FIG 74 Screws are usually supplied in batches of six in one envelope in which they can rattle around to become scratched and damaged. To get one screw out the whole six must be spilt and then maybe left to rattle around in the operating room drawers. This photograph shows how screws could easily be packed so that only one at a time need be removed from its protective covering.

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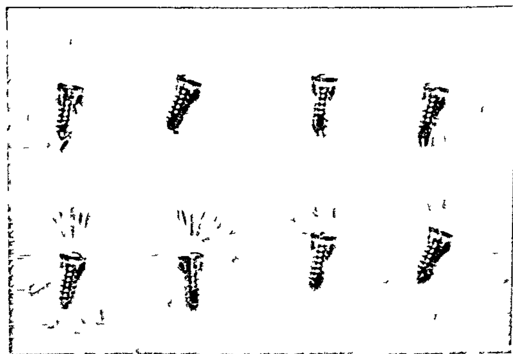


FIG 74 Screws are usually supplied in batches of six in one envelope in which they can rattle around to become scratched and damaged To get one screw out the whole six must be spilt and then may be left to rattle around in the operating room drawers This photograph shows how screws could easily be packed so that only one at a time need be removed from its protective covering

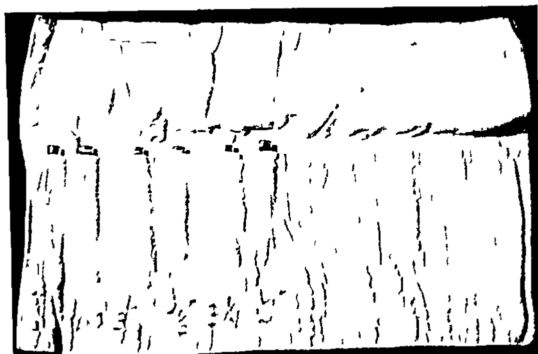


FIG 76 The same principle outlined in Figure 75 applies to plates and nails Here is a photograph of a set of hip nail in the protective bag in which they are autoclaved

from their packages It is probably wise to discard all old implants of uncertain age or composition, especially any stainless steel ones which can be attracted by a magnet They will be made of some other steel than A I S I 317 or 316 It also follows that implants made of different alloys and metals should be kept strictly separated and labeled Preferably they should only be used together when made of the same alloy and by the same company

Implants, that have once been used and certainly any that have been damaged or bent, should be discarded Any saving in money achieved by reusing implants either recovered at operation or at autopsy is probably far outweighed by the risk of failure by fracture or corrosion in the next patient A new part for each patient would be a good motto

Sterilization has been mentioned in connection with the operating room care of implants If, for any reason an implant must be autoclaved in the tray with all the rest of the surgical instruments, it should be securely wrapped to prevent its knocking against the rest of the ironmongery

CARE OF IMPLANTS DURING AND AFTER INSERTION

Here again when the implant is uncovered just before insertion, our main concern is to protect it It is probably advisable to pick up the implant with dissecting forceps or a hemostat the tips of which have a short length of rubber tubing over them (Figs 77 and 78) This gives

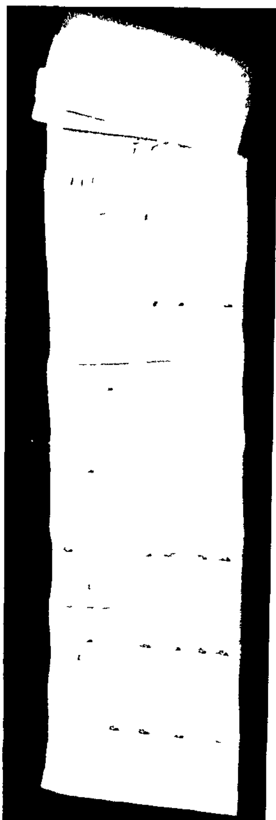


FIG 75 Rather than place screws in a metal rack where they are damaged and scratched they can easily be kept in a cloth bag with a slot for each screw On using up a screw from such a bag another one could be taken from the individually packaged screws to replace it

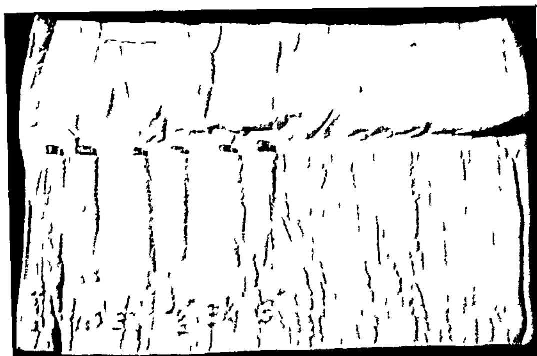


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Fig 77 This photograph shows the plastic tube protected instruments used to handle implants to prevent damage to the implant during the operation

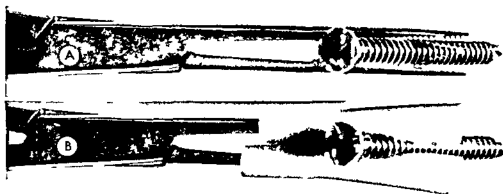


Fig 78 (A) Holding a screw with a metal instrument may crush the threads and scratch the protective surface of the implant (B) A rubber or plastic tipped instrument does not damage the implant In addition the hold is more secure

both a secure hold and avoids grasping the implant with something which will scratch its surface and will transfer metal to it This principle applies to the handling of molds and prostheses even more urgently than it does to implants that may be removed when their work is done



FIG 79 Mixed metals were inserted here and pain and disability followed Removal of the screws showed one to be of Co Cr Mo and the others of stainless steel

MIXED METALS

At the present stage of our knowledge it is advisable to avoid inserting metals of differing composition together In many instances it has been shown that galvanic corrosion follows such practices It is best to insert together only those implants made of the same alloy or element In addition, because of the possibility of the same alloys from different sources having *significantly different compositions, it is probably* wise *not to* mix implants made by different manufacturers (Figs 79–82)

THE INSERTION OF SCREWS AND PLATES

Screws should preferably be Philips or Woodruff headed to reduce screwdriver on screw slippage This will reduce the amount of metal transfer and so aid in inserting an uncontaminated inert metal Screw-holding screwdrivers are a material aid in reducing this factor although they must be used with great care so that the neck of the screw is not damaged On removing the screw holding screwdriver from the screw before tightening the last few turns, care must be taken not to bend the screw head on the shank As far as one can tell at the moment, a wrought cobalt chromium molybdenum or tungsten alloy is the best material for use in manufacturing screwdrivers meant to handle cobalt alloy screws

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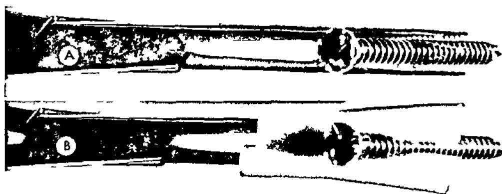


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FIG 81 (A) Radiograph of a Parham's band and a single, small screw used to attempt to hold a fractured femoral shaft Exuberant callus formation and pain later necessitated removal of the metal In the past such bands were not always made of A I S I 316 or 317 *stainless steel (B) Radiograph showing the remaining screw which has almost corroded away*



FIG 82 A Parham's band and three screws with severe bone resorption especially seen around the lower screw Probably a case of mixed metal



Fig 80 (A) This radiograph shows a Co Cr Mo mold arthroplasty of the hip with an ordinary iron nail used to reattach the osteotomized greater trochanter This may be expected to result in corrosion

Fig 80 (B) Shows the nail after removal surrounded by much rust sauce

For the A I S I 317 and titanium screws A I S I 420 stainless steel seems fairly satisfactory In general, the driver tip should not be so much harder than the screw that it cuts and damages the screw Tungsten carbide would obviously give very little metallic transfer but would cause a great deal of plastic deformation and surface damage However, tungsten carbide may prove very useful for the manufacture of drills, osteotome ends and scissors [9]

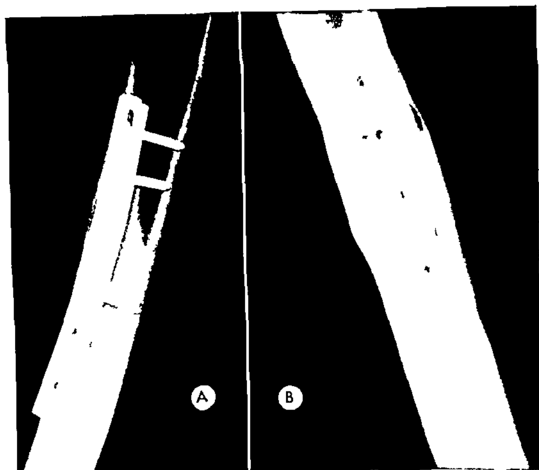


Fig 84 (A) This radiograph of a plated femoral shaft shows sound union and reformation of the medullary cavity Severe local pain and tenderness necessitated removal of the implants (B) Radiograph following removal shows dense sclerosis around each screw hole

Drilling of Pilot Holes

Drilling of the bone before inserting a screw is often done through the holes in a plate clamped over the reduced fracture It is, in the first place inadvisable to let unprotected clamp blades damage the plate They can be covered with rubber tubing In the second place a guide should be used so that the drill bit does not come into contact with the plate Much metal transfer and other damage to the plate ensues on such an accidental contact (Figs 83 and 84) Guards are available to protect the plate holes

The drill itself, preferably a hand one is a material source of metallic contamination to the pilot hole in bone the softer the drill the greater the contamination The amount of transfer is always greater from a new drill It would certainly help if each new drill were first run through a dry piece of beef bone a few times Apart from this it should probably be made of an alloy very similar in specification to the implant but much harder

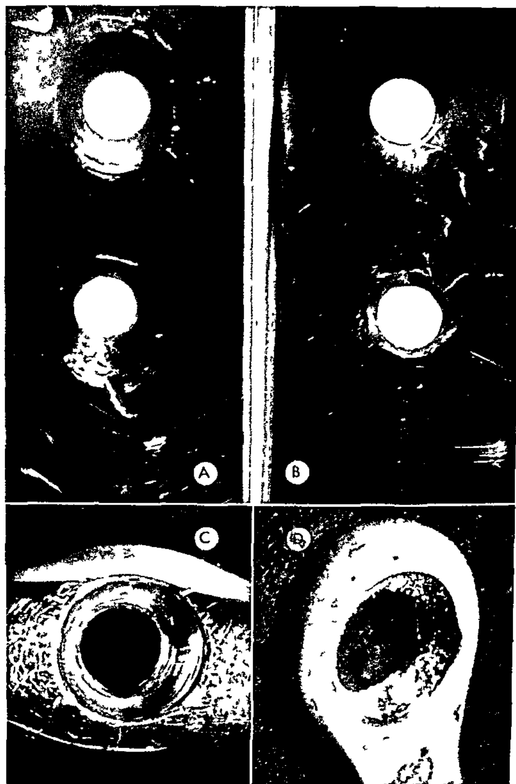


Fig 83 (A B C and D) Photographs of four plates which have been damaged by allowing the rotating drill to touch them As much as 2 mg of drill bit metal may be transferred to the plate Corrosion might be expected to follow

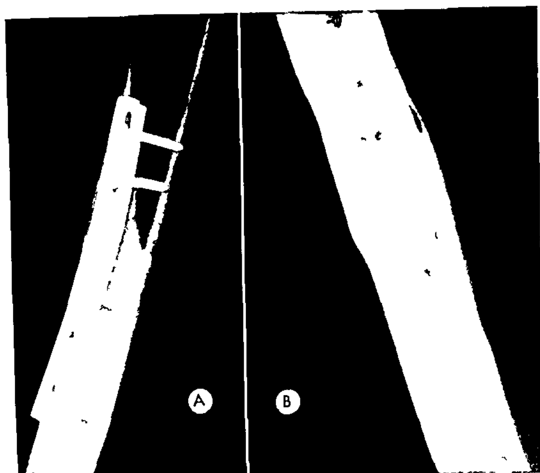


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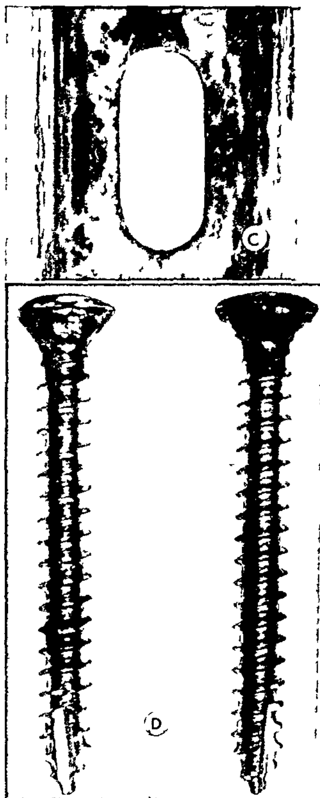


FIG 84 (C and D) Photographs of the corroded plate and screws Note the deep holes that have appeared in the undersurfaces of the heads of the screws In contrast the lower ends of the screws are relatively unaffected Perhaps the instruments used to insert these implants triggered their corrosion

Broken Drill Points and Other Metallic Foreign Bodies

Broken drill points, especially if they are made of a nonstainless tool steel but probably in any case, should be removed if corrosion is to be avoided. An implant cannot be expected to remain relatively inert if in contact with such an alloy. Mixed metals are present and corrosion will probably follow (Fig 85). This advice is also applicable if the end of an osteotome breaks off.[10]

Plating and screwing in the presence of any metallic foreign body is a hazard corrosion-wise. Shrapnel and bullets fall under this category and it is advisable to remove any metal that may be near or in contact with an implant.[10] The presence of multiple metallic foreign bodies near a hip would argue against using a mold or prosthesis for arthroplasty unless the patient had a short life expectancy.

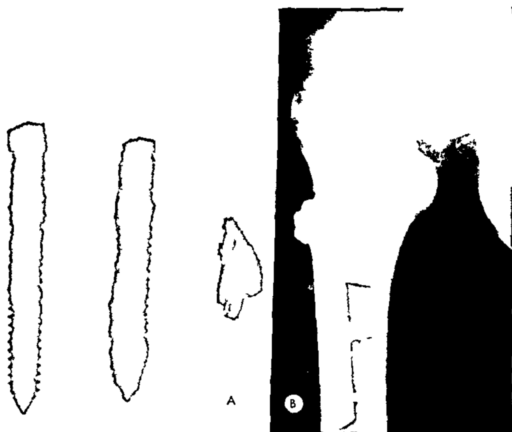


Fig 85 (A) This photograph shows two broken and corroded screws and the broken end of a drill bit which was left in when the screws were inserted. Severe corrosion resulted. (B) When this intertrochanteric appliance was inserted a drill was broken left in at the lowest drill hole. *If this implant remains in the patient for a long period corrosion may be expected.*

The Use of Hammers

Hammers are notorious for their tendency to shed flakes of metal in a wound. It is hardly fair to expect an inert implant to remain so if it is in contact with such fragments. Nylon face hammer heads may be one answer. However, these also flake off and Nylon is not free from troubles when left in the tissues.[11] It is often, however, a fairly simple matter to protect the wound with towels while using a hammer. Obviously the danger does not arise if one is working on the patient's side and gravity takes the fragments to the floor, *i.e.*, while nailing a fractured neck of a femur.

Metallic transfer is also a danger if the hammer is used directly on an implant. The use of punches merely means that transfer will occur from punch to nail. Any bare metal that touches an implant should probably be made of such an alloy that a minimum of transfer occurs or, if it does occur, that it is less dangerous, *i.e.*, use A.I.S.I. 420 punches for A.I.S.I. 316 and titanium implants and a cobalt alloy punch for the two cobalt alloy type implants.

Use of Guide Wires

The nailing of fractured necks of femur under x-ray control requires the use of guide wires along which the nail is subsequently driven.

One danger here is the use of graduated wires with a small circular groove for each unit of length (Figs. 73 and 86). After some time in service, corrosion may attack these crevices and lead to a weakening. One day the advancing end of the nail will snap the wire and drive it into the pelvis (Fig. 73). It is advisable not to have grooved guide wires but rather, if the surgeon wants them marked, to have alternating colors or some such device to mark each centimeter.

Metal in Sepsis

Metal is probably never the cause of sepsis, presuming adequate sterilization. It may, however, prevent the body from dealing with it once a wound has become infected. Once the interface between metal and body tissues is infected, the metal holds open an abscess cavity which the body cannot obliterate until the metal is removed. In addition, it is highly probable that the conditions existing around a metal implant in an infected case, *i.e.*, pH, reduction oxidation potential and oxygenation, will cause or accelerate corrosion processes.

In the presence of infection it is advisable to remove metal as soon as it is practical (Figs. 87 and 88).



Fig 86 Radiograph shows bending of a guide wire by a hip nail Occasionally this may be because the wire impacts inside the nail and is driven forward by it The guide wire should always be able to drop through the cannulated nail aided only by gravity when tested pre-operatively

Bending of Plates and Nails

There is a constant temptation to bend plates to fit the exact outside contour of a bone This is often quite unavoidable but it is wise to limit such bending of metal as much as is feasible

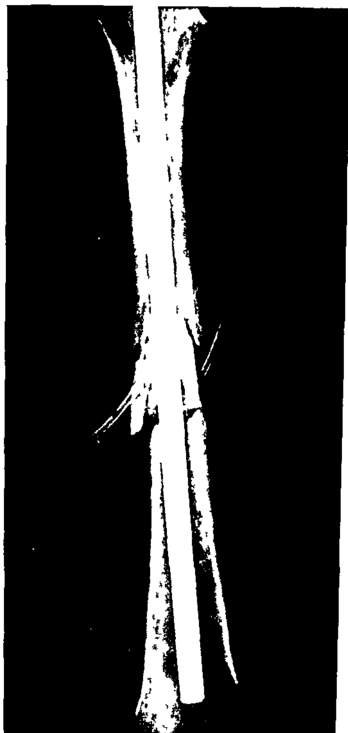


FIG. 87. Radiograph of a fractured femoral shaft with an intramedullary nail in place. Infection is present with necrosis of a section of the shaft. Through and through irrigation is being used. In the presence of infection it is probably wise to remove all metal. Metal prevents the encroachment of living tissues and keeps an abscess space open all along its borders.

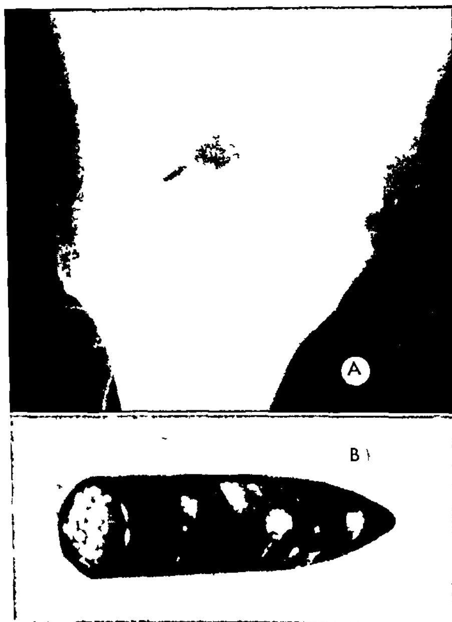


Fig 88 (A) Radiograph showing a bullet in the proximal end of the tibia Pain persisted for some years The bullet is surrounded by dense sclerotic bone Is this corrosion or infection? Removal of the bullet revealed that it really lay in a Brodie's abscess (B) Photograph of the corroded bullet

One can break a wire by bending it back and forth until it snaps So it is with a plate or nail Every bend weakens the structure at the apex of the bend Stresses and strains are introduced into the crystalline structure and under corrosive conditions stress corrosion cracking may occur Fatigue may also attack such a weakened area

In certain instances choice of another design of plate may eliminate the necessity for bending metal (Fig 89) If metal must be bent, then it



Fig 89 (A) Radiographs of a Milch Batchelor arthroplasty showing the necessity for bending the plate to fit the osteotomized femur (B) A plate made to fit the osteotomized femur avoid the necessity for bending and damaging the implant This anteriorly angled osteotomy plate hold a McMurray osteotomy

is better to have a gentle bend over a wide area than a sharp bend over a small area The instruments used to bend plates often damage them at the points of maximum pressure (Fig 90) By cushioning the force of direct pressure with a small piece of rubber or plastic much can be done to prevent this indentation and scratching

The Use of Wire

Stainless steel wire is often used by surgeons In the state delivered from the manufacturer the wire if made out of A I S I 316 or 317 stainless steel will probably be fairly inert However as soon as it is kinked, twisted or knotted then it is no longer stainless Broken wire sutures can often be seen on x rays of old laparotomy scars Wires and bands around bones have been thought to cause dissolution of bone by pressure This is probably true to a certain extent but not entirely Often the

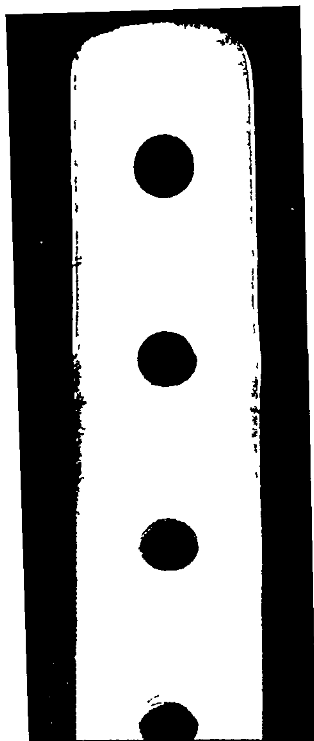


Fig 90 Photograph of a bent bone plate showing the sharp indentations along its edges where the bending irons have damaged it If the plate must be bent it may be wise to protect it with cloth rubber or plastic

bone goes on atrophying and disappearing long after the wire has ceased to bear actual contact with it Sometimes this may be caused by another implant next to it being of another alloy or it may be caused by corrosion of the wire because of damage done during its insertion Great care is needed if wire is not to corrode in the body (Figs 91 and 92)

Is It Always the Metal's Fault?

Obviously, it cannot be Often enough failure of a metal implant by fracture or corrosion follows on some unforeseeable complications This



Fig 91 Radiograph of wire suture in a patella One wire suture has broken This is very liable to happen at the site of twisting where the metal is deformed



Fig. 92 Radiograph showing a wire suture around a united fracture of the tibia. Trouble was of late onset and a zone of bone atrophy can be seen around the wire. Pain and tenderness necessitated removal of the wire. Corrosion of stainless steel wire may occur without fracture of the wire.

may be sepsis. It may be aseptic necrosis of a femoral head. It may be because too much has been asked of the metal. Charnley[1] has pointed out that the force exerted on a plate holding a fractured femoral shaft is enormous if the unsupported leg is lifted up by the patient. This lesson is applicable in many instances were internal fixation is expected to hold two bone ends together unaided by external splintage. Sometimes there is little danger, but often it is great (Figs. 93 and 94).

Take the case of the hip prosthesis. In walking one mile a person puts his full weight on each leg about 1000 times. The forces on the head of the femur amount to several hundred pounds per square inch. This force in even a sedentary life is repeated between 5000 and 10,000 times daily, not counting the added thrust of rising from a sitting position. In 365 days we get $1\frac{1}{2}$ to $3\frac{1}{2}$ million impacts a year. And this in a corrosive medium! We must not indeed expect miracles from metals.

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Fig. 91. Radiograph of wire suture in a patella. One wire suture has broken. This is very liable to happen at the site of twisting where the metal is deformed.



Fig 94 This radiograph demonstrates nonunion of a fractured humeral shaft The two top screws are loo e History revealed no postoperative immobilization The metal should not be bl imed

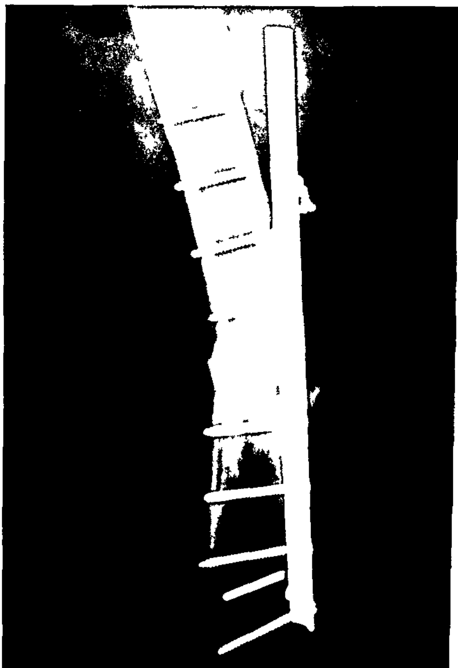


Fig 93 Was it the metal implant's fault? Probably not in this case Inadequate post operative immobilization of this fractured femur probably snapped the upper screws Such a long plate required extensive stripping of bone which may cause avascular necrosi In any case nonunion followed



Fig 96 In some cases implants which must stay in the body for many decades may cause pain and disfunction by even minimal corrosion In the case illustrated here however absorption of the femoral head and neck has led to a varus position of the mold Perhaps the bone was rendered avascular during surgery? The metal implant cannot be blamed

obviously good surgical thought must back up the performance of even the most ideal metal implant

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Take the case of the plated long bone When nonunion occurs one wonders was it really the shape of the screw slots? Or did the periosteal stripping and destruction of the nutrient artery at the operation so devitalize the bone that delayed union was a foregone conclusion (Figs 95 and 96)?

One could multiply these examples *ad nauseum* Suffice it to say that

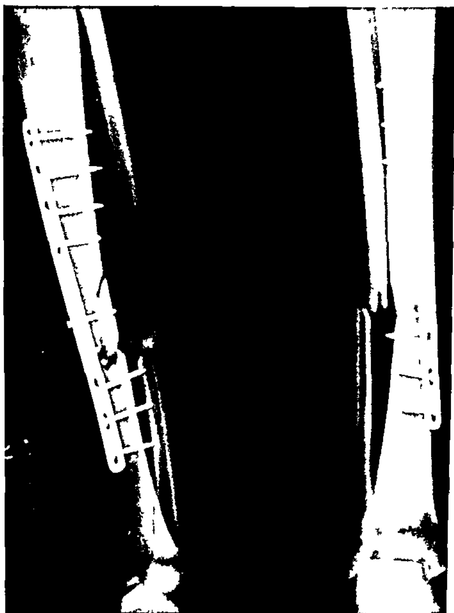


Fig 95 Radiograph of a plated tibial fracture Nonunion followed Again one cannot blame the implant metal Perhaps a shorter plate would have maintained bone apposition adequately?

6

BONE AS A STRUCTURE

Charles O Bechtol, M D

The architecture of a single bone when analyzed with relation to the forces which it must transmit in supporting the body and acting as an attachment for muscles and ligaments indicates that the bone is a prime example of the relationship of structure and function Bone when analyzed by standard engineering techniques represents a nearly perfect adaptation to the principal stresses which are placed upon it with development of the maximal amount of strength with the minimal amount of material In analyzing the component parts of a bone we begin with the joint cartilage which is the bearing surface (Fig 97) This cartilage has at least a limited power of self repair, providing it is not subject to major injury, and offers great durability The cartilage, however, has no mechanical strength and is quite flexible It is supported by the sub chondral plate of bone and the subchondral plate is in turn supported by a system of trabeculae Each individual trabeculum ends at approximately right angles to the surface of the subchrondral plate These trabeculae then course in such a way that they reflect the known engineering principles in the transmission of stress[1] They are supported at right angles by stiffening trabeculae, once again a known engineering principle in the support of long thin columns The trabecular system transmits force to the cylindrical shaft of the bone A cylinder has long been recognized as an extremely efficient method of transmitting force, particularly when the force may represent compression, bending, twisting or tension Although an I beam will support slightly more bending tension than a cylinder of the same cross sectional area, it can do this only in one direction The I beam is extremely weak when placed under a twisting force The cylinder thus represents the ideal shape for the central portion of the bone As seen in Figure 98, it is more than 400 per cent as strong as the same amount of material made into a solid rod At the opposite end of the bone the same sequence of events is found, the force transmitted by the cylindrical shaft transferred to a system of

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trabeculae which end up at right angles to the surface of the subchondral plate which again supports the cartilage joint bearing surface It should be recognized that the forces applied to the bones and joints are very high Inman has calculated that in standing still on one leg the pressure through the hip joint represents approximately 2½ times body weight[2] and the momentary forces during running and jumping must be fantastically high and represent many times body weight

EXPERIMENTAL WORK RELATING TO STRUCTURE AND FUNCTION OF BONE

Experiments were carried out to determine the relationship of the breaking strength of the paired right and left bones of experimental animals Preliminary attempts to cause these fractures by applying force couples to the ends of the bone were unsuccessful because of frequent diagonal tension failures A reliable method of fracturing the bones was discovered to be the simple center loading of the bone while supporting it at each end The bones were supported on wooden dowels of appropriate diameter spaced by turnbuckles and the center load was applied

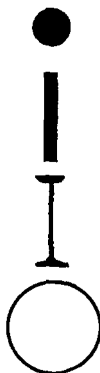


FIG 98 This demonstrates the relative strength of a solid bar a simple beam an I beam and a cylinder all made of the same amount of material If the cylinder is considered to be 100 per cent the resistance to bending of the solid bar in a vertical direction is 350 per cent the I beam is 588 per cent and the cylinder is 533 per cent It should be observed however that the cylinder will resist bending in any direction whereas the simple beam and the I beam are rather weak in bending to the side

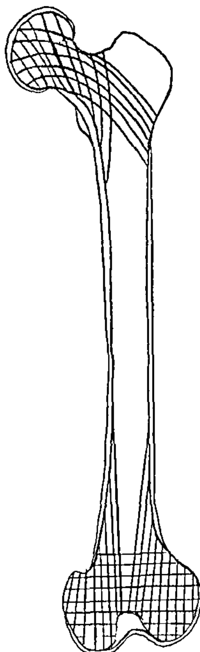


Fig 97 This schematic drawing shows bone as a force transmitting system The joint cartilages at the end of the bone are the bearing surface These are supported by a subchondral plate of bone which is in turn supported by a bony framework the trabecular system This trabecular system follows the known engineering laws for transmitting forces by means of a series of narrow columns These narrow columns are supported at approximately right angles by other similar columns The trabecular system then transmits the force to the cylindrical shaft This shaft reflects the well known engineering principle that a cylinder is the most efficient structure for its weight to resist all types of forces—compression tension bending and torsion

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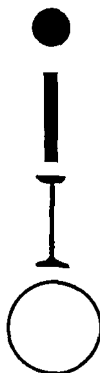


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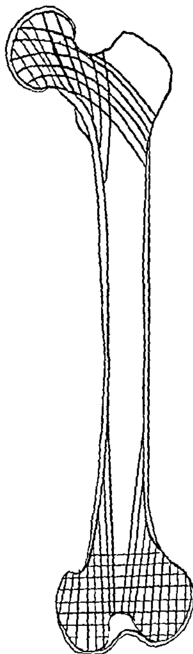


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trabeculae which end up at right angles to the surface of the subchondral plate which again supports the cartilage joint bearing surface It should be recognized that the forces applied to the bones and joints are very high Inman has calculated that in standing still on one leg the pressure through the hip joint represents approximately $2\frac{1}{2}$ times body weight and the momentary forces during running and jumping must be fantastically high and represent many times body weight

Experimental Work Relating to Structure and Function of Bone

Experiments were carried out to determine the relationship of the breaking strength of the paired right and left bones of experimental animals Preliminary attempts to cause these fractures by applying force couples to the ends of the bone were unsuccessful because of frequent diagonal tension failures A reliable method of fracturing the bones was discovered to be the simple center loading of the bone while supporting it at each end The bones were supported on wooden dowels of appropriate diameter spaced by turnbuckles and the center load was applied

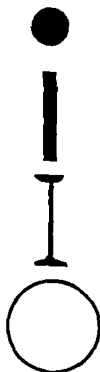


FIG 98 This demonstrates the relative strength of a solid bar a simple beam an I beam and a cylinder all made of the same amount of material If the cylinder is considered to be 100 per cent the resistance to bending of the solid bar in a vertical direction is 350 per cent the I beam is 588 per cent and the cylinder is 533 per cent It should be observed however that the cylinder will resist bending in any direction whereas the simple beam and the I beam are rather weak in bending to the side

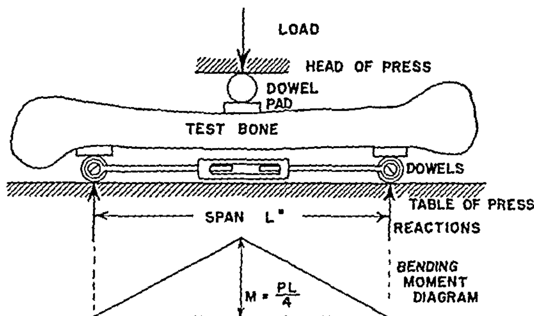


Fig 99 This shows the method of supporting the bone in the press The span L was the same for each pair of bones but was varied from one pair of bones to the next depending on their length The bending moment diagram indicates that the force is maximal immediately under the center load on the bone

through a similar wooden dowel (Fig 99) It was found necessary to protect the bone by pieces of piano felt about ¼ inch thick Otherwise the dowels would cause local cracking of the bone leading to unwanted fractures in this area Using this method it was found possible to cause the bone to fail by tension opposite the point of application of the center load Analysis of the stress applied to the bone under these conditions shows this to be the point of greatest tension The shape of the fracture produced in this fashion is typical of the bending fracture seen clinically The fracture runs approximately half way across the bone from the tension side at right angles to the surface and then curves off toward the end of the bone in a typical shear trajectory (Fig 100) If this bone



Fig 100 This shows the typical picture of a bone broken by bending The straight transverse crack indicates the portion caused by tension failure and the oblique fracture follows the so called shear trajectory The dotted line indicates the other half of the shear trajectory In most cases this is not broken off When it is separated it is called the so called butterfly fragment which should be more correctly called a shear fragment

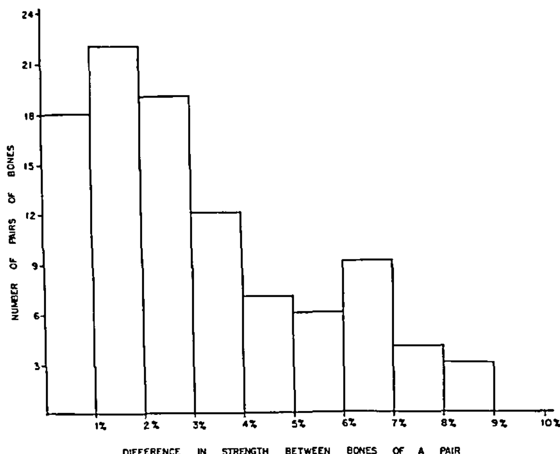


Fig 101 This bar graph shows the results of breaking 100 pairs of bones of experimental animals and is expressed as the percentage by which the breaking strength of the bones deviated from the mean of their breaking strength This represents a truly remarkable relationship of structure and function

is observed on the following day a similar curved crack will be found extending toward the opposite end of the bone made visible by seepage of oil from the marrow cavity This is familiar in clinical fractures as the so called butterfly or triangular fragment and apparently is potentially present in almost all such bending fractures even though it may exist only as a fine crack and not have actually have separated off

Experimental Results

One hundred pairs of bones were fractured by this method * They were femurs and tibias from dogs sacrificed in acute cardiac experiments Gross inspection of the bone showed no evidence of previous fracture or disease process and none of the animals had been subject to experimental procedures which might impair the strength of their bones Figure 101

* This and subsequent experimental work was carried out at Yale University School of Medicine and the School of Engineering in cooperation with Mr Henry Lepper Expenses were defrayed by a grant from the Lrdk and Prange Foundation

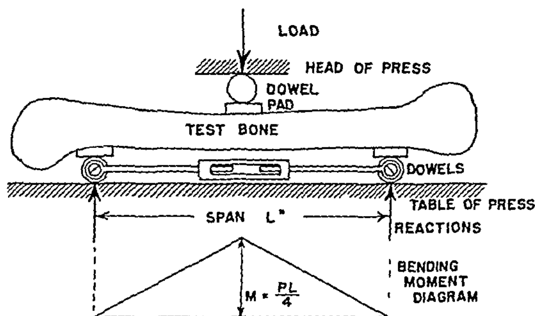


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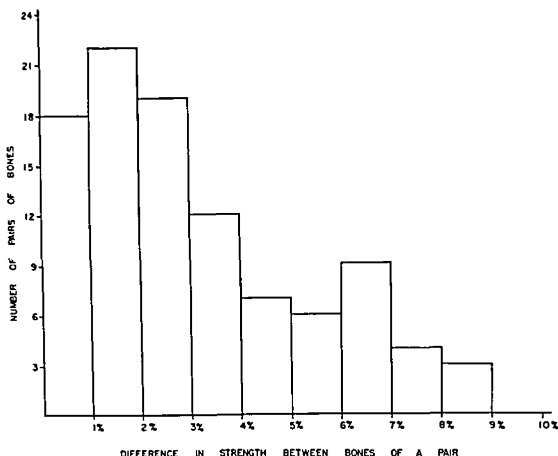


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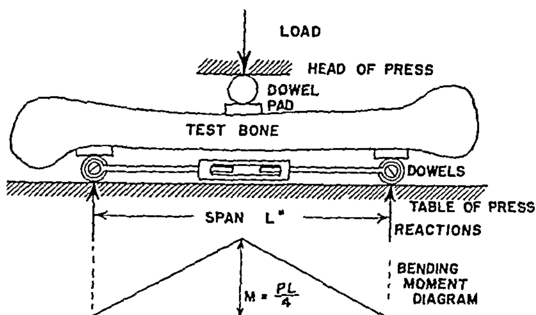


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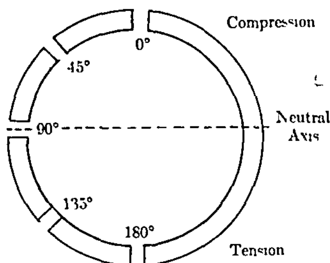


Fig. 102. This is a cross section of the bone showing holes drilled in different position. The dotted line represents the neutral axis. The hole drilled through this axis is neither in tension nor compression. The holes above it are in compression and those below it in tension. The two holes on the tension side of the bone reduced the breaking strength of the bone by about 30 per cent. The hole through the neutral axis and the holes on the compression side did not reduce the breaking strength of the bone. (These holes were approximately 20 per cent of the diameter of the bone.)

A series of thin ground sections of human bone of various ages carried out by Frost in the Yale Orthopaedic laboratory indicated a very great divergence in the size of the Haversian systems and Volkmann canals (Fig. 103). In addition to this he demonstrated that in older samples of bone the number of osteones containing living osteocytes became reduced, large portions of the bone being devoid of living cells and apparently lifeless. Cracks caused by the grinding technique were much more frequent in this avascular bone (Fig. 104). He was further able to demonstrate by staining the sections with alizarin before grinding that some fatigue cracks must exist in this avascular substance during the life of the individual. These cracks, whether fatigue cracks existing during life or artifacts in the grinding, existed only in the avascular bone and failed to propagate through the bone of the living Haversian systems. Testing these sections with a micro hardness tester indicated that the avascular bone was harder but more brittle than the bone of the living osteone.

Greenstick Fractures

In testing the bones of some young macaque rhesus monkeys, greenstick type fractures were regularly produced. This bone is less brittle than adult bone to a startling degree, a bend of 5 to 10 degrees frequently being apparent before the greenstick fracture occurred. The greenstick

shows the difference in breaking strength of the paired bones This is expressed as the percentage by which the breaking strength of the bone deviated from the mean It will be seen that the greatest deviation was 9 per cent One standard deviation was calculated to be 2 4 per cent This represents a truly remarkable relationship of structure and function and it would be difficult to obtain similar results by testing pieces of wood or metal of similar size As would be expected the length, diameter, wall thickness, and other measurements of these bones differed widely from one animal to the next However, in each individual pair of bones they showed very minimal differences One surprising observation during this experiment was that at the moment of fracture, the bones may fly apart violently apparently because of the release of the stored up energy on the compression side of the bend The bones were loaded at a uniform rate to produce fracture in 10 to 20 seconds Very slow loading (more than one hour) was found to slightly reduce the breaking strength of the bone

Since bone is a brittle material it would be expected that any defect produced in its structure would lead to considerable reduction in its breaking strength The following experiments were carried out to determine this weakening effect

The Weakening Effect of a Drill Hole in Bone Related to Its Position in Tension or Compression

Holes were drilled in bone using standard twist drills The holes were placed at the point of center loading in the experiment They were oriented 180 degrees, 135 degrees, 90 degrees, 45 degrees and 0 degrees away from the point of application of pressure In each case the hole was drilled in one bone through one cortex, the other bone being used as the control The holes were approximately 20 per cent of the outside diameter of the bone Holes drilled on the tension side of the bone at 180 degrees and 135 degrees from the point of application of force showed a weakening effect on the bone of about 30 per cent plus or minus 10 per cent The hole at the neutral axis (90 degrees) and those on the compression side (45 degrees 0 degrees) showed no weakening effect This corroborates the findings of Evans Pederson and Lissner on small pieces of bone indicating that bone is considerably stronger in compression than tension During these experiments no attempts were made to calculate the actual force on the bone at the point of break since it was felt we possessed insufficient knowledge as to the variation of the strength of bone in various parts of the same bone Experimental work of Lissner and Evans has indicated considerable variation in the strength of bone removed from different portions of the same bone

FIG 104 This is a thin ground section of bone from an older individual The living osteocytes about the Haversian canals are heavily stained Avascular portions of bone between the Haversian systems can be seen as lighter unstained material Cracks caused by grinding are demonstrated through this avascular bone They do not however continue to be propagated through the vascularized portion of the bone This indicates that the avascular bone is harder but more brittle than the living bone substance Prepared by Dr Harold Frost

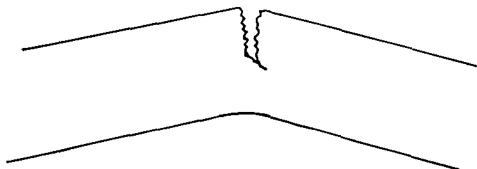


FIG 105 This demonstrates a greenstick fracture with a tension failure The remaining portion of the bone demonstrates a remarkable degree of flexibility

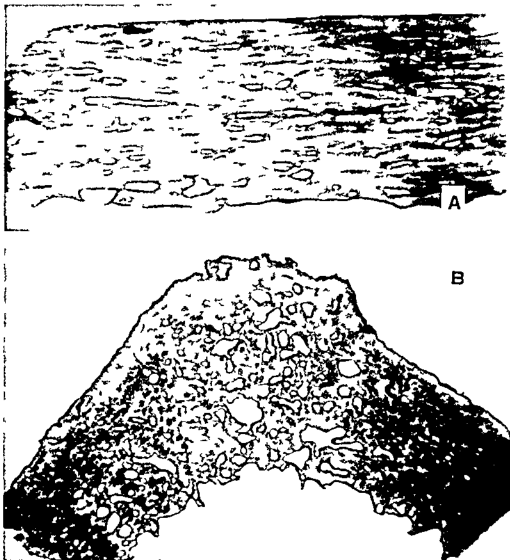


Fig 103 (A) A thin ground section of human femur which appears solid to the naked eye but actually contains many large vascular spaces (B) A cross section of the linea aspera It can be seen to contain many large vascular channels Prepared by Dr Harold Frost

fractures were of two types Some bones failed on the tension side with a simple transverse crack extending half way across the bone (Fig 105) Other bones failed on the compression side In these a curved tongue of bone caused a fracture across approximately half the bone, the failure apparently occurring as a shear failure with the fracture line extending forward from the convex surface of the crack at an angle of about 45 degrees toward the marrow cavity (Fig 106) The flexibility of the remaining half of the bone was most spectacular, further bending to 30 or 40 degrees being frequent before complete failure and in one case a bend of 100 degrees occurring before final failure This corroborates clinical

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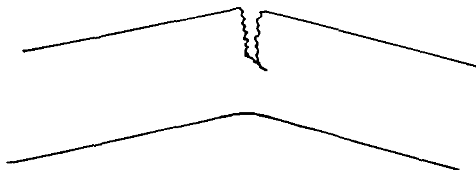


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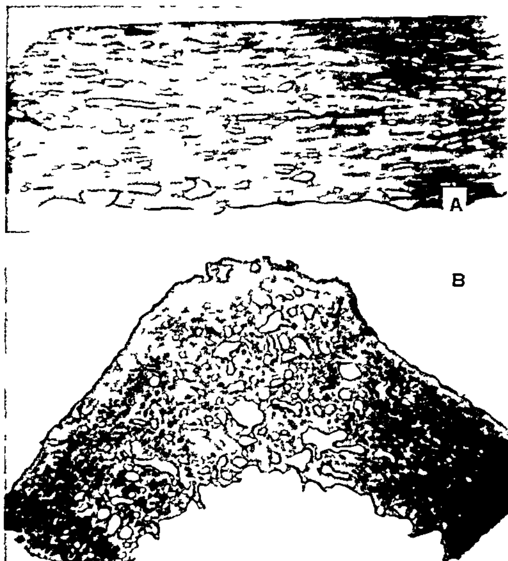


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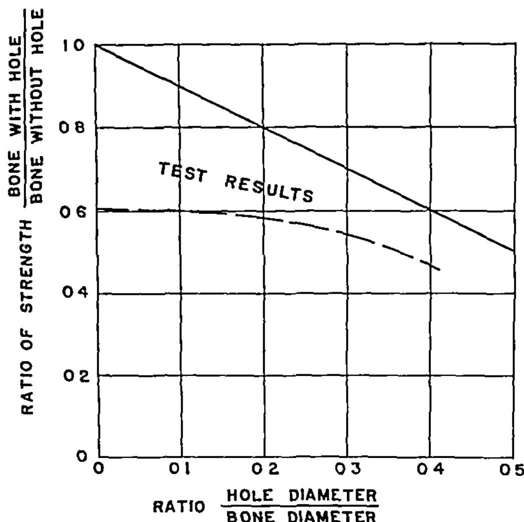


Fig 107 This figure compares the theoretical weakening effect of drilling holes in bone of various sizes with the actual experimental results The theoretical weakening effect is based upon the actual amount of bone removed and represents the solid line The test results are summarized by the dotted line and indicates that the additional factor of having the small holes act as a sharp notch was probably also of significance There was considerable scatter in these results of plus or minus 15 per cent

about 20 per cent of the bone diameter since its weakening strength will be nearly as great Holes larger than 40 per cent of the bone diameter have a very considerable weakening effect

Effect of a Split While Drilling The Hole

In drilling some of the larger holes it was observed that the drill might catch on a piece of bone while penetrating the marrow cavity (Fig 108) If the drill was then roughly forced ahead a small chip would occur at this point starting a small fracture in the bone In these cases the breaking strength of the bone is found to be very greatly decreased, being

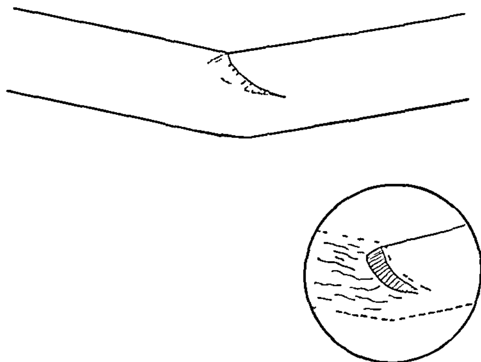


FIG 106 This demonstrates the method of green stick fracture when the failure is on a 45 degree shear plane on the compression side and a curved tongue of bone with the fracture surface slanting inward toward the marrow cavity at 45 degrees telescopes inside the concave portion of the curved fracture Once again the remaining portion of the bone remains intact through an amazing degree of further flexion

experience in children's fractures and indicates the marked flexibility of young human and monkey bone

In contrast bones of new born rabbits were found to be quite brittle

THE EFFECT OF THE SIZE OF THE HOLE ON THE BREAKING STRENGTH OF BONE

With the use of different size twist drills holes were drilled at the 180 degree position at the point of greatest tension stress opposite the force applied to the center of the bone Size of the hole was compared to the outside diameter of the bone and is expressed as a percentage Hole size varied from about 3 per cent of the bone diameter to a little more than 40 per cent of bone diameter The very small hole gave surprisingly great *reduction in the breaking strength of bone* and as would be expected in a substance such as bone which is not a homogeneous structure there was a rather wide scatter in the results (Fig 107) It was evident that the weakening effect of these small holes far exceeded the simple removal of bony substance This must reflect the fact that a small hole is a stress concentrating defect similar to a sharp notch From these results it can be concluded that there is no advantage in making a hole smaller than



Fig 109 This compares the standard twist drill for metal with the improved drill for use with bone The improved drill on the right has a narrow chisel point at its tip The angle of the tip of 90 degrees The cutting face of the drill has been reduced to 0 degrees The sharp edges of the spiral flute have been dulled The drill in the photograph is made of vitallium which will neither corrode while being autoclaved nor break even though it may be bent in a 180 degree arch



FIG 108 This shows a twist drill penetrating the cortex of the bone with a portion of bone being caught by the curved flute of the drill Forcing this drill roughly ahead will chip off a piece of bone and greatly weaken the breaking strength of this bone

weakened by as much as 60 or 80 per cent from the breaking strength of the control bone

It was felt that it might be possible to adapt a twist drill to the particular problems of drilling bone and consultation was accordingly arranged with the Greenfield Tap and Die Company regarding the specific problems encountered in drilling bones The following criteria were considered important in the design of the drill for bone (Fig 109)

1 The drill should not walk on the surface of the bone when the hole is first started This allows the drill to be placed accurately in the center of a hole in the metal plate and will prevent it from moving toward the side of the hole as the drilling is started This will prevent the drill



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from damaging the metal plate and also will accurately center the screw This quality is even more important after the drill has penetrated the first cortex of the bone and enters the second cortex If the surface of the second cortex is slightly uneven or at an angle the drill will tend to walk on this surface and because the drill is firmly held in the first cortex it may easily break off as it is driven to one side by the walking of the point

2 The angle of the drill tip should be 90 degrees It is common practice in the manufacture of twist drills to use a 90 degree point in substances such as plastics and bakelite to prevent the chipping of these substances Since bone is similar to these substances the 90 degree point should reduce the chipping of the bone The 90 degree point has an additional advantage in that it allows the drill point to make contact with the second cortex of the bone at a greater angle than the 56 degree point which is standard in metal drills

3 The cutting face of the drill should have a zero rake (be parallel to the direction and progress of the drill) This has two advantages First, it prevents the drill from catching as it emerges from the cortical surface of the bone and driving the drill ahead to chip out a piece and secondly it remains sharp longer

4 The sharp edges of the spiral flute should be dulled so that any wobbling of the drill in the process of drilling the hole will minimize the reaming of the hole to a larger size Even under the best operating conditions there is always some wobbling of the drill and some reaming effect Tests carried out in the laboratory in this regard show that even with the bone clamped in a vise and the drill hole made with a hand drill as carefully as possible the hole was always 2 or 3 sizes larger than the drill which was used

5 The drill should be made of a substance which cannot be corroded in the process of sterilizing in an autoclave Both vitallium* and stainless steel have been satisfactory in this regard Although carbon steel metal drills are made of much harder metal and will hold their point much longer under ordinary conditions, this metal is very easily corroded in the autoclave and is thus dulled before it can even be used for the first time in surgery Under the conditions in surgery the vitallium or stainless steel drills will stay sharp much longer

6 The metal from which the drill is made should not be brittle Carbon steel can be bent only a few degrees before it snaps off and this has been a frequent experience under actual operating conditions Both vitallium and stainless steel are quite malleable and can be bent more than a right

* The drills tested were supplied through the courtesy of The Austenal Laboratories

angle before there is any danger of breakage. This is felt to be an excellent safety factor.

The Effect of Irregular Defects in the Bone

Defects in bone such as saw cuts, donor sites for removal of bone graft, and so on, will weaken the bone mainly according to two factors: first, the amount of bone removed from the total circumference of the bone, and second, the presence of any sharp cracks or saw cuts extending out from the edges of the defect. The weakening effect of the saw cuts or splits can be reduced by drilling a hole at the end of the split. The ideal method of removing a bone graft from the surface of the tibia, for example, would be to drill four holes at the anticipated corners of the bone graft and to run the saw cuts into these holes and avoid the sharp corners. The holes should be $\frac{1}{2}$ to $\frac{1}{4}$ the width of the bone graft removed, or a single large hole the full width of the bone graft could be made with a brain burr. This, however, might destroy considerable portions of potential bone graft material.

The Effect of Placing a Screw in a Drill Hole

Drill holes of appropriate size were made in each of a pair of bones as would be done in preparation for placing of the ordinary bone screw. A bone screw was then drilled into one of the pair as would ordinarily be done in an operative procedure. The holes were placed at the 180 degree position in order to be under maximal tension and the bones were broken as has been described previously. Twenty pairs of bones were used in this experiment. It was found that the bone in which the screw had been placed was somewhat weaker than the bone containing only the drill hole, and this was in the proportion that would be expected had a slightly larger hole been drilled in the bone. The effect was approximately that of drilling the hole the same size as the outside diameter of the screw threads. As far as its weakening effect in bone, then, the placing of a screw in the hole merely enlarges this hole to the size of the screw threads with the concomitant weakening effect.

The effect of filling a drill hole with the round shank of a drill which was a very tight fit was next determined. Equal drill holes were made in each of a pair of bones. They were approximately 20 per cent of the bone diameter. The round shank of a slightly larger drill was then carefully inserted into one drill hole so that it would be a snug fit and the two pairs of bones were broken as described above. The presence of the round shank had neither weakening nor strengthening effect on the bone.

The Weakening Effect of a Plate Fastened to the Bone with Screws

An even greater weakening effect upon the bone was found than in the presence of a single screw The plates were of appropriate lengths for the bones used They were either two holed plates or four holed plates and were fastened firmly to the bone by the use of the screws through all the holes available The end screw was placed on the tension side of the bone at the point of greatest tension stress The weakening effect on the bone as compared to the control bone was about 40 per cent as opposed to the weakening effect of a single screw of about 30 per cent The reason for this is thought to be that the presence of the plate actually stiffened a portion of the bone, and thus in addition to the presence of a screw in the bone which would in itself have a weakening effect, the fact that this was a place in which the stiffness of the bone (or total cross sectional area of bone and plate combined) made a sudden change added an additional stress concentrating factor and these two factors then added up to a greater weakening of the breaking strength of the bone

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7

REPLACEMENT OF LIVING TISSUE

Charles O Bechtol, M D

The weight bearing structural elements of the body are the bones They follow well known laws of mechanical design Bones, however, have one very remarkable quality in that only under the most extreme circumstances are they subject to failure by fatigue Fatigue failure of a structural material is that quality which causes the material to break after it has been repeatedly bent to a small degree The bending may be so small as to be almost imperceptible and the piece of material may not be bent so far that it assumes a permanently bent position and in some cases it may take many million bends before fatigue failure will finally occur When the critical number of bends has been reached however, the material will snap in two as though it were a brittle substance This type of fatigue failure happens to bone under only the most extreme conditions It is called march fracture and this name indicates that it usually occurs in army training when someone from sedentary life is suddenly subjected to the rigors of vigorous training marches Even under these circumstances only a very small percentage of the trainees develop fatigue fractures, usually in one of the small metatarsal bones of the foot The only other situation in which we observe such fatigue fractures are in conditions which make the bones of the body exceedingly weak because of some abnormality of the general metabolism of the body Bone thus demonstrates the extremely important quality of self repair and it is this which poses a very difficult and sometimes insoluble problem when we attempt to replace a portion of bone with some type of nonliving substance

When we are asked to define what constitutes the quality of living tissue we usually think in terms of motion, growth, or ability to reproduce itself However, when we enter the field of attempting to replace living tissue with some artificial device we are immediately struck by the amazing ability of this tissue to continuously repair itself by a process which we would call 'maintenance' if related to machinery When we

give this matter a little further thought we have always been aware of some of these characteristics. Hair, fingernails, and toenails are continuously replaced and although the process is less spectacular the skin of our entire body is always being gradually worn away and replaced from underneath. This continuous replacement of the skin is perhaps most dramatically demonstrated in chemistry class when a drop of silver nitrate may permanently and deeply stain the superficial layers of the skin. In a week or two these layers are gradually replaced and the stain spots will disappear. However, when we attempt to give an amputee a cosmetic replacement by giving him a plastic cosmetic glove, we find ourselves faced with a severe problem of staining the surface of the glove. In order that this cosmetic glove not be too expensive its durability should be at least from six months to one year. However, even with the most extreme care the glove will gradually be stained during this time with various materials it will contact, and we then can truly appreciate the remarkable qualities of normal human skin and the constant replacement of the superficial layers which goes on. In the use of an external type of prosthetic appliance such as an artificial limb or a brace, the maintenance problem is not too severe since the device is readily accessible for replacement of parts, oiling joints, refinishing of the surface, and so on. However, in internal prostheses or devices such repairs are not readily carried out.

In contrast to the external prosthesis such as the artificial limb which is accessible for repair, once we have placed this internal prosthesis into position it must remain there for the lifetime of the individual and we shall be unable to inspect it routinely, give it such maintenance as it needs, or replace it when necessary. We know from long experience that metal parts placed in the body to take the place of portions of bone can undergo fatigue failure and break. Because of the extreme difficulty of the experiments involved we do not know what the fatigue limits are and we cannot at the present time give the engineer exact design criteria for his use in the development of these replacement appliances. The reason for this lack of information is the considerable time involved in these experiments, the difficulty of placing recording instruments within living tissues for long periods of time, and the impossibility with our present instruments of measuring the stresses to which these devices are subjected within the living body and keeping an accurate record of the number of times these stresses are applied.

Even the normal slight bending of a bone may eventually lead to the fatigue failure of metal. There are examples of fractures in which a rod has been placed down the marrow cavity of the bone to maintain position during fracture healing. After the fracture is completely healed in

TABLE 7*

Physical Properties of Three Materials

Property	Stainless Steel A.I.S.I. 316 (18-8 S Mo)		Human Bone (Femur)	Vitallium Casting
	Annealed	Cold Worked		
Ultimate tensile strength (p.s.i.)	80 000–90 000	100 000–150 000	13 000–17 700	90 000–110 000
Shear strength (p.s.i.)		—	16 800 (parallel to long axis) 5 700–13 300 (transverse)	—
Compression strength (p.s.i.)	—	—	18 000–24 000	—
Yield point 0.2 per cent offset	35 000–55 000	50 000–125 000	—	62 000–85 000
Elongation	Min. 40%		—	7.6%
Reduction in area	Min. 50%		—	11%
Modulus of elasticity (p.s.i.)	28.5 × 10⁶ p.s.i.		2.82–2.95 × 10⁶	30.0 × 10⁶

*From Proceedings Instructional Courses, A.A.O.S., Vol. XI, p. 95, 1954.

some cases the rod has not been removed. After several years of walking around with the rod in place the x-rays have shown that the rod is broken in two because of repeated small bendings within the bone. This brings up an additional problem in design, since one of the reasons for the fracture of this rod is the difference in flexibility (modulus of elasticity) of bone and the metal rod.

The metal is considerably less flexible than the bone. This is only one of the problems posed by living tissue in its attempted replacement. A second problem is that the tissue is alive only because it can receive blood supply from the surrounding tissue and in the case of bone any appliance which is placed in the body must not cover too much of the surface of the bone because its blood supply will be interrupted and the bone will die. This necessarily places a severe limitation upon the design of many of these devices which could be made much stronger and more durable if they could be made of sufficient size. Their size, however, must be limited because they would otherwise interfere with the blood supply of the bone to which they are attached. A similar size problem is that related to the spaces available within the body. Beneath the skin only so much space is available and this is all occupied by normal structures—bone, muscle, nerves, blood vessels, fat, ligaments, and tendons. The replacement device then cannot be much larger than the bone which it is to replace since it would otherwise press on the surrounding muscles, nerves, and blood vessels, and perhaps even protrude through the skin with resultant disturbance of these tissues.

Conclusion

It will be seen from this discussion that attempts to design replacement devices for bony portions of the body are immediately limited by many factors No material is known which has the quality of self repair which is possessed by normal living bone The design of any replacement device is limited to approximately the size of the bone for which it is substituted This frequently means that we must accept a device of less strength than we might desire, and this device must be so designed that it will not interfere with the blood supply of the bone and surrounding tissues or death of the bone and these tissues may follow, leading to a poor result We can only conclude then from the present state of our knowledge that we are unable to offer any devices which can even partially replace bone in its full normal function and any device must then necessarily offer only limited function The ravages of disease and injury, however, force us to attempt these difficult tasks since the only alternative is to leave our crippled patients even more limited in function than what we can offer them with some type of replacement prosthesis in many cases The pattern of our past experience indicates that many patients can be benefited by replacement of parts of the body with various substances, and results from year to year show a steady encouraging improvement

8

FRACTURE HEALING IN A TEMPORARY SPLINT

Charles O. Bechtol, M.D.

Fracture healing is an orderly process beginning with the blood clot and tissue debris which surrounds the fracture and ending with the formation of bony callus. In uncomplicated cases this bony callus follows known engineering principles achieving maximal strength with a minimal amount of material. Proper formation of this bony callus is primarily dependent upon adequate blood supply in the surrounding tissues. The great majority of fractures can be adequately held by means of plaster of Paris casts or traction and the healing time is such that stiffness of the adjacent joints will recover and no permanent disability will ensue. There are a small number of fractures, however, in which this is not possible and some type of internal fixation is desirable either to maintain the bony fragments in opposition or to allow earlier mobilization of joints and soft tissue. The three problems encountered in internal fixation are (1) the use of a substance which is not irritating to the tissues, (2) the use of a material and design which is sufficiently strong and durable to maintain position until the fracture has healed, and (3) design of the surgical approach and placement of the fixation material in such a way that the blood supply of the healing fracture will not be seriously interfered with. It is, of course, impossible to carry out internal fixation of a fracture without interfering in some degree with the blood supply in the area of the healing fracture.

As a result of the basic problems stated above, it is usually impossible to design a method of fixation which will have more than a very small amount of the strength of the intact bone. In many cases it will be necessary to use some additional type of fixation such as traction or plaster of Paris cast. Here a compromise must be made between the strength of the fixation device and the amount of blood supply disturbed in healing. Metal plates which are applied to the external surface of the bone can obviously be made stronger by making them larger or by using

multiple plates This probably will disturb the process of fracture healing as more and more of the bone surface is exposed and covered with the metal plates Studies comparing initial breaking strength of cadaver bone with the strength of this bone after having been plated by one of the usual methods indicate a great variation in the strength of the plating procedure because of many variables, but in every case the plated bone is only a fraction as strong as the original intact bone[1] Kuentscher stresses the need for using very large intramedullary nails if they are to approach the strength of the intact bone The size nails which he recommends will not fit the normal marrow cavity of the bone but require that the marrow cavity be reamed out with a special tool for their insertion It must be here emphasized that this discussion relates only to a single test on the bone and a single test on the internal fixation device Under actual conditions of use in the body the fixation device is, of course, subjected to fatigue failure because of repeated bending stress It will be remembered in the previous discussion that bone exhibits fatigue failure only under the most extreme conditions, whereas metals used in bone fixation are definitely subject to fatigue failure In this category, then the internal fixation devices must be described as markedly weaker than the intact living bone These fatigue failures of internal fixation devices have been seen to occur clinically in a period from a few weeks to a few months after their insertion in cases in which excessive stress has been put upon them There are at present no data available on the forces necessary to cause this fatigue The extreme difficulty and complexity of carrying out such an experiment is obvious and at present we must rely on clinical observations which indicate that fatigue and overstress failures can occur with all types of metal internal fixation devices Studies by Lindsay and Howes indicate that in the process of fracture healing there is a gradual and *steady increase in the breaking strength of the fracture callus as it devel*ops until it finally exceeds the strength of the intact bone when completed These experiments were carried out in rats and parallel clinical experience in human fractures One of the insoluble problems in the design of devices for internal fixation is that most of them must be made of several parts which must be fastened together This is usually a mechanical necessity as in the case of plates and screws The screws are necessary to fasten the plate in position and yet between the screw head and the hole in the plate a condition known as fretting corrosion can occur This consists of an infinitesimally small motion between the two surfaces of metal and among its results is the scraping off of the protecting oxide layer on the surface of the metal thus leading to accelerated corrosion in this area The small cracks thus established will act as a source

of weakness in the plate and may lead to its early fracture This is a common problem in all such types of fit in engineering and is very difficult and many times impossible to deal with

The problem of a permanent replacement of a portion of bone with some sort of a metal or plastic substitute is even more difficult First difficulty is the fastening of this internal prosthetic device to the bone There must be as wide an area as possible through which this force is applied Excessive pressure on the bone will cause local necrosis and absorption of the bone The force must likewise be spread over as much of the metal or plastic surface as possible since local areas of stress concentration might lead to an early fatigue fracture of the prosthetic device Nature presents us with an interesting experiment in this regard in her design of the epiphyseal plate at the end of the various bones These are much more strikingly demonstrated in a specialized quadruped such as the sheep or deer and are much less highly developed in man or the great apes The epiphysis has good strength in compression but is relatively weaker than the surrounding bone in shear, as is seen in fractures through this area and in slipping of the upper femoral epiphysis The area of weakness lies between the epiphyseal cartilage and the metaphysis A striking example of the design of epiphyseal lines is seen in the knee where the distal end of the femur has a very irregularly shaped line (Fig 110) The force transmitted from the tibia to the femur will vary within about 135 degrees depending upon the degree of flexion at the knee If the epiphyseal cartilage is removed by boiling the bones it will be found that when the epiphysis is returned to its normal position it is quite stable because of the configuration of the epiphyseal plate even though the bones now have no adhesive force holding them together The epiphysis at the top of the tibia is an entirely different situation Here, regardless of the degree of knee flexion force is transmitted approximately in the direction of the axis of the tibia and therefore the epiphysis is subjected only to simple compression This epiphysis is nearly flat with only very slight irregularity With regard to the design of the prosthetic device, extreme limitations are imposed upon the amount of material that can be used since it must fit within the tissues of the body and cannot be much larger than the part of the bone which it is replacing Great care must be used to avoid sharp notches or sudden changes in cross sectional areas since these will all serve to concentrate stress and lead to fatigue fracture At the present state of our knowledge it is doubtful if any of these devices can survive normal activity for a long period of time Most of them probably succeed because the extremity is used to a relatively limited degree

multiple plates. This probably will disturb the process of fracture healing as more and more of the bone surface is exposed and covered with the metal plates. Studies comparing initial breaking strength of cadaver bone with the strength of this bone after having been plated by one of the usual methods indicate a great variation in the strength of the plating procedure because of many variables, but in every case the plated bone is only a fraction as strong as the original intact bone[1] Kuentscher stresses the need for using very large intramedullary nails if they are to approach the strength of the intact bone. The size nails which he recommends will not fit the normal marrow cavity of the bone, but require that the marrow cavity be reamed out with a special tool for their insertion. It must be here emphasized that this discussion relates only to a single test on the bone and a single test on the internal fixation device. Under actual conditions of use in the body the fixation device is, of course, subjected to fatigue failure because of repeated bending stress. It will be remembered in the previous discussion that bone exhibits fatigue failure only under the most extreme conditions, whereas metals used in bone fixation are definitely subject to fatigue failure. In this category, then the internal fixation devices must be described as markedly weaker than the intact living bone. These fatigue failures of internal fixation devices have been seen to occur clinically in a period from a few weeks to a few months after their insertion in cases in which excessive stress has been put upon them. There are at present no data available on the forces necessary to cause this fatigue. The extreme difficulty and complexity of carrying out such an experiment is obvious and at present we must rely on clinical observations which indicate that fatigue and overstress failures can occur with all types of metal internal fixation devices. Studies by Lindsay and Howes indicate that in the process of fracture healing there is a gradual and steady increase in the breaking strength of the fracture callus as it develops until it finally exceeds the strength of the intact bone when completed. These experiments were carried out in rats and parallel clinical experience in human fractures. One of the insoluble problems in the design of devices for internal fixation is that most of them must be made of several parts which must be fastened together. This is usually a mechanical necessity as in the case of plates and screws. The screws are necessary to fasten the plate in position and yet between the screw head and the hole in the plate a condition known as fretting corrosion can occur. This consists of an infinitesimally small motion between the two surfaces of metal and among its results is the scraping off of the protecting oxide layer on the surface of the metal, thus leading to accelerated corrosion in this area. The small cracks thus established will act as a source

REPLACEMENT OF JOINT SURFACES

The use of polished metal against the fibrocartilage which will develop on an opposed bony surface has been shown to be successful. Long experience with the Smith-Petersen cup has indicated that in most cases a successful fibrocartilage to metal joint can be established and lead to reasonably painless though somewhat limited function of the joint[3] There is little experience as yet with metal to metal or metal to plastic contact in joints. Many basic data are needed in this area.

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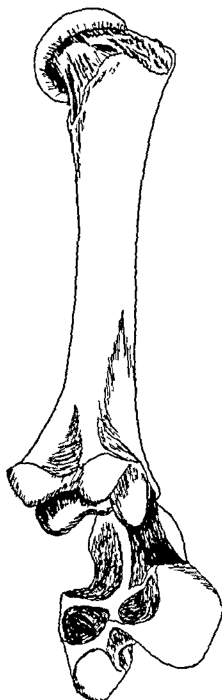


FIG 110 This demonstrates the markedly irregular shape of the epiphyseal line of the distal end of the femur of a sheep The epiphyseal line has been softened by boiling to allow removal of the epiphysis The femur is viewed posteriorly and the epiphysis has been tipped forward When the epiphysis is placed on the femur it shows surprising stability to compression forces applied to any portion of the articular surface of the knee joint

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9

INTERNAL FIXATION WITH PLATES AND SCREWS

Charles O Bechtol, M D

The problems of internal fixation *represent one of the facets of the* age old mechanical problem of fastening two pieces of material together Within the limitations imposed by the living body tissue all possible types of fasteners have been used In every case compromises must be made which are mechanically undesirable but biologically necessary With rare exceptions internal fixation devices applied to bone are made of metal It is the only material available at the present which has sufficient strength This single fact overrules any other problems or undesirable characteristics which metal may have

Cancellous Bone

The structure of cancellous bone is in a sense similar to wood in that a nail driven into it will crush and break the material it is driven through usually without causing any large splits in the structure After the nail is driven in it is gripped with reasonable firmness by the surrounding bone so that it can hold the fragments from being further displaced by small strains Repeated strains of the magnitude of the ordinary use of the extremity however will frequently dislodge the nail The cancellous bone has a thin shell of cortical bone on its surface and because of the orientation of the osteons (Haversian systems) this surface cortex will have a tendency to split It is frequently wise to drill or chisel a hole in the cortex to allow the starting of the nail or staple Ordinary round nails will hold small fragments in position They possess however, no power *of preventing rotation of the fragment* The familiar tri flange Smith Petersen nail does prevent this rotation The tri flange shape however is relatively weak in resisting bending forces and when used in conjunction with a plate as is commonly done in intertrochanteric fractures greater resistence can be obtained by the use of either a T shaped nail with the tube for the guide wire at the bottom of the T, or an I beam

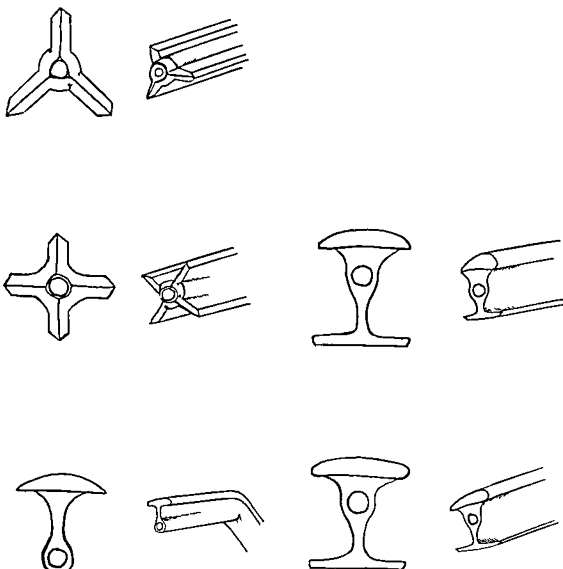


Fig 111 The top two sketches represent the standard tri flange Smith Petersen nail and the four flanged nail as used in the MacLachlan nail The three T shaped or I beam shaped nail shown in the lower portion of the figure are 300 to 400 per cent stronger than either the three flange or four flange nail These are at the present all experimental devices

shaped nail* with the guide wire tube placed in its lower portion (Fig 111) Depending upon the exact design, such nails will be from 2 to 4 times as strong in resistance to a bending force as the tri flange nail

Staples are a suitable method of holding together two pieces of cancellous bone for example, an arthrodesis of the knee Their use in producing epiphyseal arrest is well known and the pressure of the growing epiphysis requires the use of at least three staples on each side The use of screws in cancellous bone is quite successful A hole of appropriate size should be drilled before introduction of the screw There are no data available

* The experimental nail were cast in vitallium by the Austenal Laboratories

at the present as to which type of thread will hold best in cancellous bone However experience has shown that the grip of threads is usually so good that the head of the screw can be pulled through the thin outer cortex without stripping the threads out of the cancellous bone The use of either a large sized head on the screw or a washer is desirable under such circumstances

Cortical Bone

Cortical bone is quite dense and its physical characteristics are very similar to those of very hard wood in which it is impossible to drive a nail *There is a moderate tendency in cortical bone to split in a longitudinal direction* Benninghoff[1] has demonstrated that decalcified cortical bone shows a definite pattern of split lines which in general run parallel to the principal stresses on the bone and also in general parallel the orientation of the osteons The split lines, however, can usually not be obtained at areas of tendon or ligament attachment Because of these characteristics fixation of cortical bone requires that a hole be drilled to allow entrance of the fixation apparatus or that it be held by circumferential pressure

Types of Fasteners Used

Commonest types of fasteners used are wire bands, screws, bolts, staples and nails both round and possessing various types of fin-

Wire

Fragments of cortical bone can be held together by the use of wire placed through a drill hole in each fragment The amount of fixation afforded is very small compared to the strength of the intact bone and supplemental support with a cast is usually necessary The fixation of the ends of the wire by twisting them together frequently leads to breakage of the wire at this point particularly if the wire was forcibly twisted in an attempt to tighten it Examination of the wire with a hand lens when it has been twisted in this fashion usually shows splits in the first turn of the wire The proper method of fastening the ends of the wire together is tying a square knot It should be recognized, however that the knot weakens the breaking strength of the wire by about 25 per cent If more than one loop of wire is used each loop should be tied spearately Because of its inherent weakness the largest possible size of wire should be used in any fixation If the wire is accidentally kinked in being put in place it should be discarded since the kink area after straightening out will probably be considerably weakened

Bands

The use of bands to hold spiral fractures has been a controversial subject for many years. The original Parham bands were made of brass and were intended to be removed after the fracture had healed. If they were left in place, the brass, because of its toxic effect on the tissues, produced a circumferential notch in the bone. This notch, acting as a stress concentration groove, would frequently produce a fracture at this area. With the use of our present noncorrosive metals the chance of producing such a groove in the bone beneath the Parham band is comparatively slight. If such a groove should be seen in the x ray, however, the Parham band should be removed. Experiments were carried out using an inert alloy of cobalt.* Eight Parham bands were placed around the femurs of dogs and allowed to remain in place for 4 to 6 weeks. At the end of that time there was no evidence of grooving beneath the bands and when these bones were broken and the breaking strength compared to that of the control bone no weakening effect was demonstrated. In summary, a band placed around a spiral fracture is a mechanically sound method of immobilization. Biologically, it has the advantage of being comparatively small in size but has the disadvantage of requiring dissection of the soft tissues completely around the bone, and the potential danger of causing a groove in the bone with a subsequent fracture at this site.

Screws

Screws are suitable to hold fragments of cortical bone together, particularly if the fracture is an oblique or spiral one. Before placing such screws in position or even drilling the holes it is important that the fracture be reduced by whatever means is appropriate to its final position. The use of screws to pull the fracture into position is quite dangerous since the alignment of the holes may change, leading either to a split of the bone or stripping of the threads.

It is usually best to use the lag screw principle in holding spiral fractures. A lag screw has threads placed distally but a smooth shaft proximally so that in tightening the screw the cortex in contact with the distal threads will be pulled toward the cortex which comes in contact with the head of the screw. If the screw is fully threaded and the threads are engaged in both the proximal and distal cortex the two fragments are usually pushed apart as the cutting flutes of the screw are engaging the distal cortex. Since lag screws are not usually available in a large number

* The experimental alloys were supplied by the Austenal Laboratories.

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fixation [illegible]
[illegible]
support [illegible]

Nature's Healing About a Bone Defect

In view of the weakening effect of placing a screw in bone it was next determined whether this effect persisted or whether nature would carry out some compensatory process. Accordingly a single screw was placed in the femur of an anesthetized dog using standard surgical technique. The screw was placed in the same position as the screws in the experiments which demonstrated their weakening effect. The animals were then allowed to survive for a period of 30 and 60 days which is adequate time in a dog for bone healing to take place. Eight animals were used. During this time they were given several intraperitoneal injections of trypan blue dye. This is a supravital dye which stains new bone being laid down as does madder feeding or injections of alizarin. Trypan blue has less general toxicity than the other two, however. When sacrificed the bones of the animals were dissected out. Observation in each case showed a collar of new bone stained by trypan blue at the head of the screw (Fig 113). This collar is similar to a standard engineering design procedure in which the weakening effect of a hole drilled in any substance can be reduced by an appropriate raised collar surrounding the hole. The effect of this raised collar of bone was such that the weakening effect of the hole was balanced out and the bone bearing the screw broke at approximately the same force as the control bone. Following the break the marrow cavity was examined and found to show an increased amount of endosteal bone as well (Fig 114). This finding is not surprising when viewed in the light of all other information indicating that structure and function are very closely related in bone and that bone will respond to stresses placed upon it by laying down new bony material to compensate for these stresses.



Fig 113 This shows the screw in position in the middle of the shaft of the bone. The shaded area indicates the amount of new bone stained with trapan blue. This collar of new bone brings the breaking strength of the bone up to that of the control side.

of sizes the same principle can be applied by first drilling the hole through both the cortices in the usual fashion and then taking a second drill which is just larger than the outside diameter of the screw threads and drilling out the proximal cortex. It must be recognized that the head of the screw exerts very high pressures against the edge of the hole. If the under surface of the head is flat the danger of splitting the bone will not be as great as though the under surface is the cone, shaped to fit into a beveled hole in the plate. If such a screw is being used the hole in the bone into which the head will engage should be countersunk and excessive force should not be used in setting the screw home (see below for the use of a torque screwdriver). A spiral fracture consists of a split at 45 degrees to the axis of the shaft of the bone. This split makes one complete turn 360 degrees around the bone and is then connected from its two ends by a vertical split down the length of the bone. Because of the 360 degree turn of the spiral split, the best fixation is obtained by placing the screws at right angles to the longitudinal axis of the bone (Fig. 112). It should be noted that there is usually a small continuing spiral split in the bone beyond the ends of the actual fracture. It is usually invisible on x ray and frequently even invisible under direct observation unless some tension is placed upon the bone to demonstrate it. For this reason it may be desirable to place an extra screw across each end of the fracture just distal to the end of the actual separated fracture. The advantage of placing this screw must be weighed against the disadvantages of the additional dissection and disturbance of blood supply which may be necessary to put it into position. It must again be emphasized that the

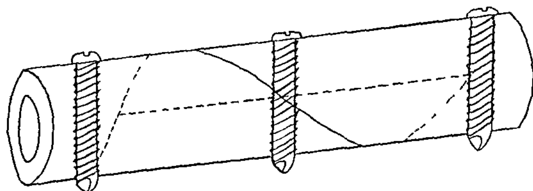


FIG. 112. This shows the 360 degree spiral fracture turn with continuing cracks in the bone beyond the ends of the spiral, the ends of the spiral being connected by a straight crack down the back of the bone. A single screw placed at right angles across the center of the fracture affords good holding power. It is frequently wise to place an additional screw at the end of each spiral crack to prevent further splitting of the bone.

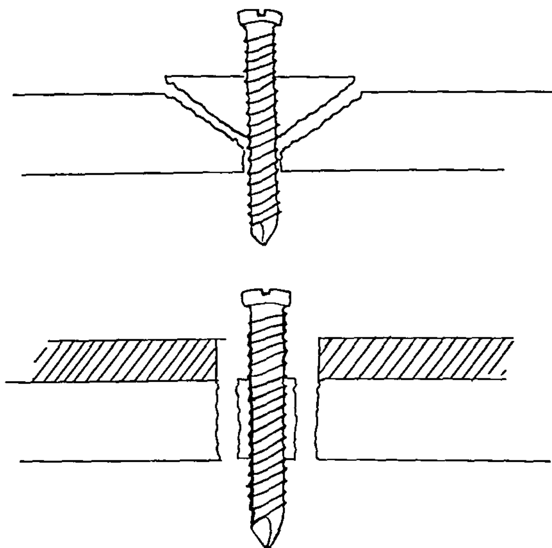


Fig 115 A screw pulled directly out of bone without counterpressure placed around the screw will pull out a button of bone This is really a test of the shear strength of bone which is usually less than the holding power of the screw If downward pressure is exerted upon the bone by a standard bone plate or a washer the true holding strength of the screw threads is then demonstrated and the shear failure of the bone is prevented

thread in which the tip of the screw which cuts into bone is a half circle, and two were modifications of the British Whitworth thread which is a V shaped thread with a rounded tip A stud bearing the threads of each experimental design was machined at the American Screw Company to close tolerances These studs were then used by the Austenal Laboratories and a number of standard bone screws using each type of thread design were cast in vitallium The screw heads and cutting flutes were of standard design to facilitate comparison with the usual types of bone screws Pullout tests were carried out through the central third of freshly dissected dog femurs and tibias This is an area in which there is little change in



Fig 114 The amount of additional endosteal bone about the screw is demonstrated as compared with the control *Left* control *Right* new bone about screw (42 days)

Experimental Work on the Design of Screws

The problem of which thread form gave the best holding power was approached in the following manner The so called pullout test in which the screw is withdrawn from the bone in the line of its axis offers the best experimental complications in determining the holding power of the screw threads in bone Preliminary experiments showed that two types of results were obtained when attempting such pullout tests (Fig 115) If the bone is supported at its ends and the screw pulled out a small button of bone will be pulled out by the screw leaving a cone shaped crater in the bone with its apex pointing downward and its sides at approximately 45 degrees to the surface of the bone This represents a shear failure of the bone and merely indicates that the bone is usually somewhat weaker in shear than the holding power of the threads in the bone Such tests give no indication of the true holding power of the screw in bone since it is really a test of only the shearing strength of the bone In order to determine the true holding power of the screw threads in bone it is necessary to exert the counter pressure on the bone immediately around the screw hole A convenient method of doing this is to put a standard bone plate in position while drawing the screw out of the bone and to exert the counter pressure on the plate Under these circumstances a greater force is necessary to withdraw the screw and the threads which have been cut in the bone by the screw will be truly stripped out leaving a hole only slightly larger than the outside diameter of the screw threads Consultation was obtained with Meunchinger of the American Screw Company in Willimantic Connecticut Five experimental screw threads were designed Three of these were modifications of the French railway

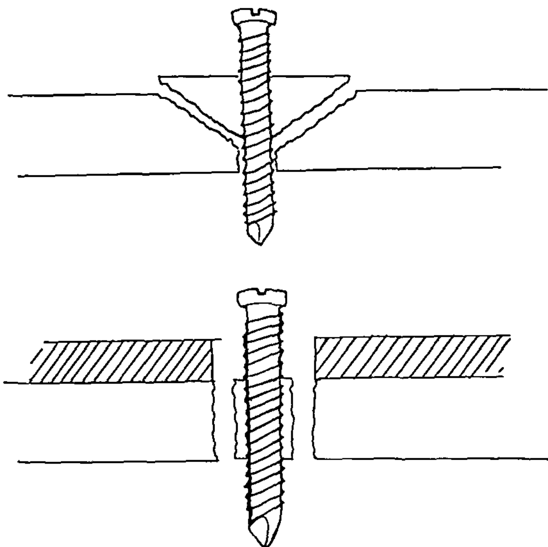


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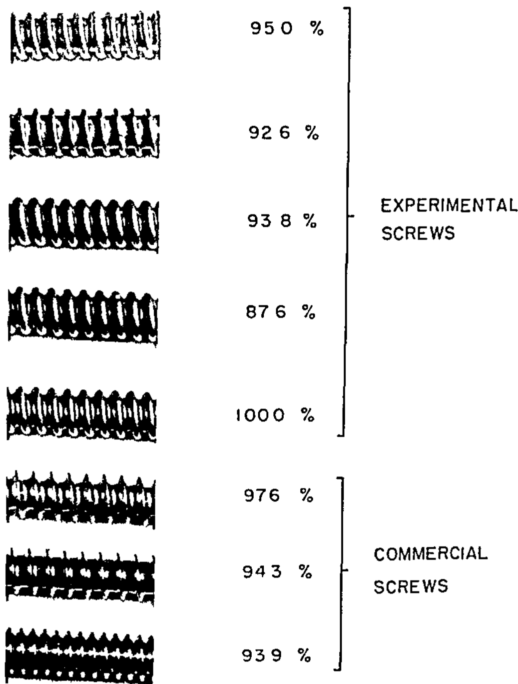


FIG 116 The five experimental screw threads are seen Their holding power is expressed as a percentage of the holding power of the experimental screw which proved to be best This is compared with the holding power of three of the standard bone screws that are commercially available The variations are considered to be within the limits of experimental error and indicate that our present thread designs are satisfactory as far as holding power is concerned

wall thickness of the bone and in which repeated pullout tests with similar screws have shown little variation in the holding power Tests were carried out only through the proximal cortex where counter pressure could be effectively applied It was felt that including the distal cortex in the test would have introduced several uncontrolled variables such as the flexibility of the cylindrical bone, as well as a good possibility that the portion of the screw in the distal cortex would pull out a button of bone rather than truly stripping the threads In order to obtain a similar substance of more uniform characteristics, pullout tests were also done using strips of plastic (methyl methacrylate) The plastic strips were 3/16 inch in thickness which is approximately the same thickness as the bone cortex used The results of the test in plastic agreed closely with the tests in bone and there was slightly less scatter in the experimental results indicating the greater uniformity of the plastic as a testing material The results of *these experiments indicated that one of the experimental* screw threads was very slightly better in holding power than the standard commercial screws and some of the experimental screws were considerably worse (Fig 116) The holding power of the coarse threaded commercial screw (standard vitallium screw) was slightly better than the holding power of the fine threaded screw (machine type thread) All of these differences were actually within the limits of experimental error and indicate for the present, at least, that there is no need to change the design of our presently available bone screws, as far as their holding power is concerned

The question of which thread design will be best to prevent early fatigue of the screw and which shape to the head of the screw will give the best holding power against the plate is as yet unsolved

Self tapping Flutes (The Problem of Cutting the Threads in Bone)

During these experiments the great importance of properly cutting the threads in the bone was apparent particularly with the experimental threads which were large in size Care had to be exercised to start the screw carefully without wobbling lest a considerable piece of bone be chipped away with a consequence of great reduction in the pullout test All tests in which such chipping of the bone or plastic was observed were excluded from the experimental results The design of a proper cutting point for the self tapping flutes of the screw appears to be a nearly insoluble mechanical problem

The following diverse requirements must be solved First the thread should not be cut in the bone by a single cutting face, but rather by a series of several cutting faces each taking a slightly deeper bite in the bone This considerably reduces the chance of chipping the bone It is

the principle of a broach in taking successive small cuts, and requires that the end of the screw be tapered, that the cutting flutes be fairly long. Secondly, the chips which are cut in the bone must not fill the cutting flutes. Long and large grooves are required, since if the flutes become filled with chips there is increased chance of splitting the bone. The only alternative is occasionally to back out the screw and clean out the flutes. This procedure would lengthen the operation at a point when time is of critical importance.

As would be expected, the portion of the screw which contains the flutes has less holding power than the undisturbed threads of the screw because a comparatively smaller amount of thread is in contact with the grooves in the bone. There is naturally a considerable variation in this decrease in the holding power depending on whether the flutes cut out are large or small, or whether two, three or four flutes are present. In general, the reduction in holding power of the fluted portion of the screw on pullout tests is 20 and 30 per cent less than the holding power of the intact screw. This characteristic then comes into direct conflict with the second requirement of cutting flutes, they should be reasonably large to make a place for the chips to accumulate. Large flutes will have significantly less holding power. One alternative, if maximal holding power is required, is to drive the screw far enough through the distal cortex so that all of the area containing the flutes lies in the soft tissues. In many cases this will be undesirable since the protruding screw will interfere with muscle or tendon action and lead to pain. The other alternative is to use a separate tap to cut threads in the bone and then remove the tap and place a screw without cutting threads in the bone. Although this method seems ideal and would be quite successful in the machine shop conditions, under operating conditions this would lengthen the procedure at a period when time is critical. The tap and the screws which it is designed to work with would have to be machined to very close tolerances and after the tap had been autoclaved a number of times and come in contact with other metal instruments while being washed its cutting flutes might be corroded or damaged. The use of a separate tapping device offers little advantage in surgery.

Two types of experimental cutting flutes were designed which showed some promise. The first was to shape the cutting end of the screw like the standard countersink used in wood with a series of 6 to 8 cutting faces and the cutting end beveled at an angle of 45 to 60 degrees. These cutting faces intersect the advancing screw thread and in a single turn of the thread produce a number of cutting points which take successively larger grooves in the bone. This type of self tapping point has the advantage of being only one or two turns of the thread longer. It does not

jam with bone chips since the bone chips fall into the hole ahead of the advancing screw. From the practical standpoint, however, it would be very difficult to manufacture since it would be very difficult to either machine or grind into the small size screws used in bone work. A second experimental cutting thread showed more promise. In this, the end of the screw was first ground to a 45 degree cone and then an X shaped slot was cut or ground into the end of the screw to the depth of a little more than one turn of the threads. This provides four progressively larger cutting surfaces to establish the groove and is self clearing of chips since they are driven ahead of the screw down the hole. It also has the advantage of being comparatively short. Once again the problem of manufacture offers some difficulties since if the two cross slots are not narrow and very accurately placed the remaining portion of metal will be too small and thin and may easily break off. It can be seen from the above discussion that there is no complete solution to the problem of the self tapping screws.

THE HOLDING POWER OF LARGER SCREWS IN CORTICAL BONE

It is generally true when a screw is fastened into a solid piece of material that a larger screw will have greater holding power than a smaller one. However, in cortical bone there was some question as to the possible advantage offered by a larger screw, since the limited thickness of the wall of the bone would hold fewer and fewer threads with the larger size screw. There was the added disadvantage that the large screw would cause a greater weakening effect on the breaking strength of the bone itself (Fig. 117). To test this, a series of brass wood screws were obtained, all of similar design, and similar cutting flutes were filed in the ends of

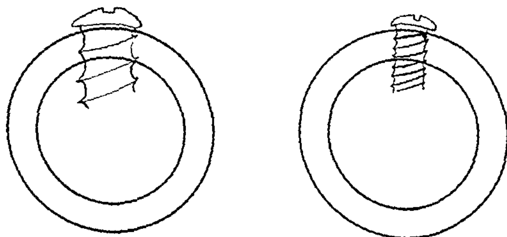


Fig. 117. This demonstrates the fact that a large screw with a similar thread pattern offers fewer threads to engage the bone than a small screw. This may explain the comparatively slight increase in holding power using a large screw.

the screws with the use of needle files Holes of appropriate size for each screw were drilled in fresh dog femurs and tibias and pullout tests were carried out using a single cortex Because of the varying size of the bones the screw size is expressed as percentage of the outside diameter of the bone The smallest screw was 20 per cent of the bone diameter and the largest 43 per cent of the bone diameter Five different sizes of screws were used A total of 20 tests were carried out When the tests were completed the bones were sawed in two and the wall thickness determined The wall thickness was approximately the same as the outside diameter of the smaller screws When the results were plotted the larger screws showed a slightly improved holding power over the smaller ones There was about the same amount of scatter in the results as seen in the other pullout tests The improved holding power of the larger screws was not more than 20 per cent better than that of the small screws In view of the fact that the use of these large screws would, first, considerably reduce the breaking strength of the bone, and, second, require the use of very large plates, which might be biologically undesirable in the process of fracture healing, it was felt that there was no advantage in using screws larger than those now generally available for the fixation of plates to cortical bone

The Force (Torque) Used in Setting the Screw in Bone

In the aircraft industry screws or bolts which may be subject to fatigue are set in at a predetermined torque This is done by means of a torque screwdriver or wrench which registers the number of inch pounds used in tightening (an inch pound represents a force of one pound applied one inch away from the center of rotation of the screw) The screws or bolts are usually tightened to about 80 per cent of the force which would cause them to be twisted off or to strip threads The problem of fastening screws into bone is rarely that of approaching the point of twisting off the screw except in very dense bone in which the threads cut in the bone will usually be stripped Attempting to remove a screw after bone healing has taken place around it and bone has grown into the self tapping flutes may result in twisting off the screw Tests using standard bone screws and a torque screwdriver* were carried out in human cadaver bone and indicated a rather wide variation in the stripping torque necessary in various portions of the bone A hole of appropriate size was drilled in the bone The screw was then threaded through a plate and driven into the bone The purpose of the plate was to act as a method of distributing the pressure over a wider area to prevent the head of the screw from splitting the bone Through most of the shaft of the bone it was impossible

*Supplied by the Apco Mossberg Company Attleboro Massachusetts

to strip the threads at 25 inch pounds This is a very considerable amount of force and it is quite difficult to keep the screwdriver bit engaged in the slot of the screw The slot in the screw head is always significantly damaged by the force of the screwdriver at 25 inch pounds of torque Approaching the ends of the bone as the cortex became thinner, the stripping torque fell off rapidly and through the cancellous portions at the end of the bone fell to as low as 5 pounds Results were similar over the articular surfaces A torque screwdriver which would withstand autoclaving was devised by the Apco Mossberg Company and in the course of a series of surgical procedures holes were drilled into the femurs at different levels and in different age groups In the younger age group the holding power in the shaft of the femur was greater than 25 inch-pounds and in the cancellous bone was 5 to 10 inch pounds In the older age group showing osteoporosis for a variety of reasons, the holding power in the shaft of the femur was several times observed to be as little as 5 inch pounds A striking example of the atrophy of disuse was observed in a hip which had been arthrodesed for many years The transmission of forces was such that the shaft appeared normal in the x ray however, the greater trochanter showed extreme osteoporosis It had not been subject to the pull of the abductor muscles for more than 10 years In the shaft the stripping torque was greater than 25 inch pounds However in the osteoporotic greater trochanter it was only 4 inch pounds The torque screwdriver which can be autoclaved offers significant help in cases of osteoporosis since a hole can be drilled into a bone in an area which will not interfere with the operation and the stripping torque of the bone determined Screws used to hold the internal fixation device can then be set at 75 to 80 per cent of this torque without fear of stripping The maximum effective holding power of the screws is thus obtained

To determine the increase in the holding power of the screw due to bone healing about the threads, the following experiments were carried out in anaesthetized dogs A screw was inserted into a hole drilled in the femur and the threads in the bone stripped using the torque screw driver The force required to strip the bone threads was recorded Five other holes were then drilled and screws set into these holes at 90 80, 60, 40, and 20 per cent of the stripping torque The screw was left in the hole which had been stripped The animals were sacrificed at intervals of 1, 2, 3, and 4 weeks and the torque necessary to strip the thread determined Stripping torque was used rather than a direct pullout test since the preparations for this test would have disturbed the hold of the screw in the bone A continuous increase in the stripping torque of all screws was noted The screw placed in a 90 per cent of the *stripping* torque did not show any initial weakening of the holding power as one would expect if bone necrosis

had occurred caused by excessive pressure The eventual holding power was about 50 per cent greater than the initial stripping torque The screw in which the threads had been completely stripped showed a similar continuous increase of holding power, although at the end of four weeks it did not approach that of the other screws It had already exceeded the initial stripping torque of the bone From this we may conclude that a screw which is accidentally stripped during a surgical procedure should be left in place, remembering that extra support will be necessary for the first few weeks if this screw was in a critical position It is probable that because of the very small size of the healing necessary around the stripped threads that this will usually occur faster than the healing of a fracture

CONCLUSIONS

Although the use of a screw to fasten either pieces of bone together or internal fixation devices to bone has very sharp mechanical limitations, it is still one of the most useful methods available because of its biological advantages Proper application with due consideration of its limitations will frequently find it the most suitable method of internal fixation

Screws and Plates

In transverse fractures the use of screws and plates to obtain some internal fixation is frequently desirable This is a typical example of the biomechanical compromises which are necessary and of the definite limitations on possible engineering design within the limitation posed by biological necessities Biologically the use of screws and plates offers the advantages of needing a comparatively small stripping of blood supply and comparatively little disturbance of the periosteum Mechanically there are a number of disadvantages (1) The bone is weakened by the drilling of holes (2) The holding power of the screw is subject to technical weakness such as a poorly drilled hole splits in the bone occurring either with drilling the hole or driving in of the screw and splits in the bone as a result of starting the screw at an incorrect angle (3) Any threaded object is inherently weak because of the stress concentration at the root of the threads particularly the first thread Fatigue failure of the screw may occur at this point (4) The holding power of the screws in the bone is limited by the brittleness of the bone This is an extremely variable factor (5) Fretting corrosion by very small movements between the screw and plate at their point of contact may start a small crack in the plate which will greatly decrease its fatigue life and may under some circumstances lead to an early break of the plate (6) The maximal holding power of a properly placed screw and plate is still far below the breaking strength of the normal bone An additional external support of the fracture will frequently be necessary

THE DESIGN OF METAL PLATES FOR INTERNAL FIXATION

As previously mentioned, although the use of a metal plate held to the bone by screws may offer many mechanical inadequacies, it is biologically desirable because of the relatively small amount of bone which needs to be exposed with the relatively smaller disturbance of blood supply in the process of bone healing From the engineering standpoint the plate can never approach more than a fraction of the strength of the intact bone, and if it were not for the biological necessities, the strongest arrangement would be a metal tube into which the two ends of the bone could be fitted Although plates as they are now designed and used rarely break, it is never possible to predict which case may be subject to great and repeated stress leading to later fatigue failure of the plate For this reason it is desirable to design the plate to be as strong as possible and as resistant to fatigue as possible In general, the stress in a plate will be any sudden change in the shape of the plate which will lead to an area of stress concentration A convenient analogy in thinking of areas of stress concentration is to imagine the shape of the plate reproduced as a trough through which water is flowing An obstruction in the center of the trough which would represent the hole in the plate will cause waves and eddys in the water and these represent areas of stress concentration Widening out the trough around this area will allow the water to flow more smoothly and this is frequently seen in plate design with the plate being made wider around each screw hole Any sudden narrowing in the plate will likewise cause a stress concentration as will any sharp notches Figure 118 shows an example of engineering tests done on a bar 10 mm in diameter which is machined down to 7 mm in its center On fatigue tests the reduction of the fatigue strength of the bar

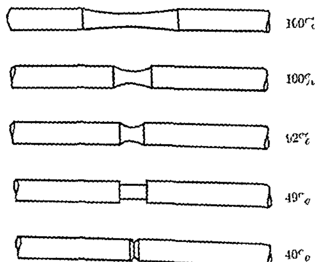


FIG 118

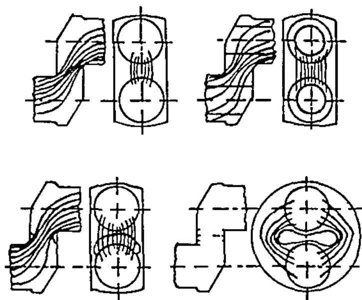


FIG 119 In this series of crankshafts each one has been made successively stronger than the previous one as far as fatigue life goes by comparatively small changes to make the stress flow in a more even pattern Although this occasionally may result in the addition of some metal it is usually accomplished by the removal of metal in the proper spot

is very little when a rounded notch is used, but a sharp notch with either square or V shaped corners very greatly reduces the fatigue strength of this bar In the design of plates the engineer is faced with the same dilemma as he is in the aircraft industry where space and weight limitations are very extreme Under these circumstances it is frequently impossible to make the part larger in order to increase its fatigue strength and the accepted procedure is to remove metal from the part in such a way that the entire structure is of nearly uniform strength and areas of stress concentration are thus avoided This is known as the "one hoss shay principle" in which all parts of the plate are of nearly equal strength A striking example of this is seen in the drawings of engine crankshafts shown (Fig 119) The crankshaft made of solid metal has the least fatigue life By making the round bearing area hollow a better distribution of stress is achieved and the fatigue life increased Small curves to avoid the sharp notch at the junction of the round bearing surface and the connecting piece also increase fatigue life Change in the shape of the connecting piece also increases fatigue life Change in the shape of the connecting piece either by making an oval hole in it or by shaping so that it is thick around the edges and thinner in the middle further increases the fatigue life It will be observed that in each of the changes the crank shaft is actually made of less metal and the improvement is made by removing metal from an area in which it is too strong rather than by adding metal to an area which is too weak In many surgical procedures

it is necessary to bend the plate to fit the contours of the bone after the operation has been completed Bending of the plate induces cold working in the metal This changes some of its characteristics and produces areas of stress concentration There is no way to avoid the necessity of bending plates in certain operative procedures We must, therefore, realize that these plates are weakened and must be given additional support The bend should be made as gradual as possible and if possible should be accomplished by tending the plate by hand over the padded edge of the table Metal bending irons, used when necessary, mar the surface of the plate and frequently make small notches which add greatly to the stress concentrating effect If this occurs it should be recognized that the plate is even further weakened Repeated bending of the plate first one direction and then the other direction in the same area, as would be done for example, if the plate had been bent too far and this had to be corrected, is exceedingly bad and it can be demonstrated that the plate falls off very rapidly in strength with each repeated reverse bend If the plate is bent too far on the first try it is much better to discard it than to attempt the reverse bend to correct the excessive initial bend

Intramedullary Fixation

The introduction of intramedullary fixation by Rush and Kuentscher opened a field which offers some biological and mechanical advantages not experienced by other methods of fixation Although this method disturbs the medullary blood supply, the blood supply of the periosteum is disturbed only if an open reduction is necessary and then usually to a lesser degree than if some type of fixation on the surface of the bone was used Under ideal circumstances the strength of the intramedullar device can be much greater than that of a plate and screws applied to the surface of the bone The holding power of the intramedullary device, however, is rapidly reduced if the fracture is near one of the ends of the bone leaving a short bony fragment From clinical experience it seems desirable that the intramedullary nail should have some hold in the bone to prevent rotation if this is possible, and if this is not possible a supplementary wire or screw at the fracture site may be in order A wide variety of shapes of intramedullary nails are available at the present time there is no convincing evidence now available as to which of these shapes is best Kuentscher has stressed in his recent article the enlargement of the marrow cavity by drilling or reaming to allow the use of a very large nail so that the strength of the nail may increase to be nearly equal to that of the intact bone Even if this is done, however, it is not possible to apply the full force to the intact bone since the bone has been weakened (1) by the fact that it is fractured and as it is forced against the nail at

the fracture site further splits may occur, and (2) in reaming out the marrow cavity of the bone the wall is significantly thinned and the bone made much more fragile and easier to split In general, it is rarely possible to allow full and unprotected use of the extremity after intramedullary nailing although with reliable patients carefully controlled use of the extremity may be possible

The Cloverleaf Nail

Since the cloverleaf nail is asymmetrical in shape its resistance to bending is different in the different directions It is strongest when the concave side of the bend is toward the slot, and weakest when the slot is on the concave side of the bend This is because the edges of the slot buckle and give way As a consequence of this when the cloverleaf nail is placed in the femur its strongest position to resist both bending and fatigue is to place the slot either laterally or anteriorly

Conclusions

The intramedullary nail offers the biological advantage of comparatively little disturbance of the fracture site and of the growth of external callus It usually offers a relatively stronger fixation than other types of internal fixation This advantage decreases as the fracture approaches the end of the bone In most cases it is possible to leave the extremity unsupported by external fixation and thus allow early joint motion and maintain normal mobility of soft tissues

The Bent Intramedullary Nail

If an intramedullary nail is bent through the accidental application of too much force it must be straightened by manipulation of the extremity to maintain the fracture in proper position The area of the bend will frequently be stiffer than the surrounding area because of the factor of cold working and therefore when the nail is straightened the correcting bend may take place above or below the original bend The resultant S shape may make this nail very difficult to remove after fracture healing is completed and it is frequently advisable to withdraw such a nail and replace it with a new straight nail The bending and straightening of a nail will always reduce its strength and reduce its fatigue life It is not always, however necessary to remove this nail and replace it with a new one As a general rule if the bend of the nail is less than 30 degrees and if there is reasonable assurance that further excessive force will not be applied it is safe to leave the nail in If the nail is bent more than 30

degrees, however, it is usually wiser to withdraw it and replace it with a new straight nail

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APPENDIX

ENGINEERING ORTHOPEDIC GLOSSARY

Stress The force or weight resisted by a structure

Strain The bend or deflection of the structure under load (stress)

Force A weight or load applied to a structure It is defined by its direction and amount

Strength Commonly means breaking strength and is the maximum load carrying capacity of the structure

Work Measured as a force acting through a certain distance in a certain length of time

Deformation The bending or displacement of a structure under load (it may be elastic deformation, or plastic deformation)

Elastic bend The range in which a material may be bent and returned to its original shape when the force is removed

Plastic bend When a material is bent past its elastic limit, permanent plastic bending occurs The result of this bend is know as plastic deformation

Tension A force pulling a structure apart

Compression A force pressing a structure together

Bending moment The effect of a force considered with relation to a point not in the line of action of the force The result of the action of the force about the point is to produce a rotation about the point Bending moment is measured as the force times the distance from the center of rotation (for example inch pounds)

Force couple Two opposite parallel forces causing rotation of the structure to which they are applied

Stiffness Resistance to deformation or bending

Brittleness Lack of plastic bend When the material has reached its elastic limit it breaks rather than undergo further bending

Toughness The ability of a structure to absorb energy by bending without breaking

Cohesion The resistance of a material to tension forces causing a tearing apart of the structure

Notch effect The concentration of force in the depth of a notch leading to breakage in this area

Fatigue The failure of a material under repeated bending

Neutral axis The portion of a beam being bent which is neither under compression or tension It is near the center of the beam and is sometimes called the axis of O stress

Modulus of elasticity The resistance of a material to deformation or bending It is expressed as stress divided by strain

Radius The curvature in any notch or corner

Fillet The smooth curvature joining irregular structures (similar to the curvature seen between the wide and narrow portion of a bone)

Permanent set The deformation or bend in a structure which remains after a plastic bend

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